

1                   **Deciding When to Submit a**  
2                   **510(k) for a Software Change to an**  
3                   **Existing Device**

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5                   **Draft Guidance for Industry and**  
6                   **Food and Drug Administration Staff**

8                   ***DRAFT GUIDANCE***

9                   **This draft guidance document is being distributed for comment purposes only.**

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20                   For questions about this document, contact (CDRH) Linda Ricci, Office of Device Evaluation,  
21                   301-796-6325, [Linda.Ricci@fda.hhs.gov](mailto:Linda.Ricci@fda.hhs.gov).

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## **Preface**

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48 <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.  
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68 **Draft Guidance for Industry and**  
69 **Food and Drug Administration Staff**

70  
71 *This draft guidance, when finalized, will represent the current thinking of the Food and Drug*  
72 *Administration (FDA or Agency) on this topic. It does not establish any rights for any person*  
73 *and is not binding on FDA or the public. You can use an alternative approach if it satisfies*  
74 *the requirements of the applicable statutes and regulations. To discuss an alternative*  
75 *approach, contact the FDA staff responsible for this guidance as listed on the title page.*

76  
77 **I. Introduction**

78  
79 This guidance, when finalized, will assist industry and Agency staff in determining when a  
80 software (including firmware) change to a 510(k)-cleared or a preamendments device subject to  
81 510(k) (also referred to in this document as “an existing device”) may require a manufacturer to  
82 submit and obtain FDA clearance of a new premarket notification (510(k)).

83  
84 For the current edition of the FDA-recognized standards referenced in this document, see the  
85 FDA Recognized Consensus Standards Database at  
86 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

87  
88 FDA's guidance documents, including this draft guidance, do not establish legally enforceable  
89 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should  
90 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
91 cited. The use of the word *should* in Agency guidance means that something is suggested or  
92 recommended, but not required.

93  
94 **II. Background**

95  
96 The regulatory criteria in 21 CFR 807.81(a)(3) state that a premarket notification must be  
97 submitted when:  
98

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99 (3) *The device is one that the person currently has in commercial distribution or is*  
100 *reintroducing into commercial distribution, but that is about to be significantly changed*  
101 *or modified in design, components, method of manufacture, or intended use. The*  
102 *following constitute significant changes or modifications that require a premarket*  
103 *notification:*

104  
105 (i) *A change or modification in the device that could significantly affect the safety*  
106 *or effectiveness of the device, e.g., a significant change or modification in design,*  
107 *material, chemical composition, energy source, or manufacturing process.*

108  
109 (ii) *A major change or modification in the intended use of the device.*  
110

111 FDA issued the original [\*Deciding When to Submit a 510\(k\) for a Change to an Existing Device\*](#)  
112 [\*\(K97-1\)\*](#) on January 10, 1997 to provide guidance on this regulatory language. As stated in that  
113 guidance, the key issue regarding 21 CFR 807.81(a)(3) is that the phrase “could significantly  
114 affect the safety or effectiveness of the device” and the use of the adjectives “major” and  
115 “significant” sometimes lead FDA and device manufacturers to different interpretations. That  
116 guidance provided the Agency’s interpretation of these terms, with principles and points for  
117 manufacturers to consider in analyzing how changes in devices may affect safety or effectiveness  
118 and determining whether a new 510(k) must be submitted for a particular type of change. This  
119 draft guidance preserves the basic format and content of the original, with updates to add clarity.  
120 The added clarity is intended to increase consistent interpretations of the guidance by FDA staff  
121 and manufacturers.

### **The 510(k) Process and the Quality System Regulation**

122  
123  
124  
125 Any guidance on 510(k)s for changes to a legally marketed device should consider the role the  
126 Quality System (QS) regulation, 21 CFR Part 820, plays in changes to devices. For some types  
127 of changes to a device, the Agency believes that a new 510(k) is not necessary and that reliance  
128 on existing QS requirements may reasonably assure the safety and effectiveness of the changed  
129 device.

130  
131 Among other requirements, the QS regulation requires manufacturers of finished medical devices  
132 to review and approve changes to device design and production (21 CFR 820.30 and 820.70) and  
133 document changes and approvals in the device master record (21 CFR 820.181). Any process  
134 whose results cannot be fully verified by subsequent inspection and testing must be validated (21  
135 CFR 820.75), and changes to the process require review, evaluation, and revalidation of the  
136 process where appropriate (21 CFR 820.75(c)).

137  
138 The net effect of the QS regulation is to require that, when manufacturers of a finished medical  
139 device make a change in the design of a device, there is a process in place to demonstrate that the  
140 manufactured device meets the change in design specifications (or the original specifications, if  
141 no change was intended). They must keep records, and these records must be made available to  
142 an FDA investigator (see Section 704(e) of the FD&C Act). For many types of changes to a

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143 device, a new 510(k) may not be required per 21 CFR 807.81(a)(3). In these cases, compliance  
144 with the QS regulation can reasonably assure the safety and effectiveness of the changed device.  
145

146 **III. Scope**

147  
148 As used in this draft guidance, “software” is the set of electronic instructions used to control the  
149 actions or output of a medical device, to provide input to or output from a medical device, or to  
150 provide the actions of a medical device. This definition includes software that is embedded  
151 within or permanently a component of a medical device, software that is an accessory to another  
152 medical device, or software that is intended to be used for one or more medical purposes that  
153 performs these purposes without being part of a hardware medical device.<sup>1</sup>  
154

155 This guidance, when finalized, will aid manufacturers of medical devices subject to premarket  
156 notification requirements who intend to modify a 510(k)-cleared device or a preamendments  
157 device subject to 510(k) (also referred to together as “existing devices”) during the process of  
158 deciding whether the modification exceeds the regulatory threshold of 21 CFR 807.81(a)(3) for  
159 submission and clearance of a new 510(k). Note that any person required to register under 21  
160 CFR 807.20 who plans to introduce a device into commercial distribution for the first time must,  
161 per 21 CFR 807.81(a)(2), submit a 510(k) if that device is not exempt from premarket  
162 notification requirements. Private label distributors and repackagers are exempt from submitting  
163 a 510(k) if they satisfy the requirements of 21 CFR 807.85(b). This guidance, when finalized, is  
164 not intended to address modifications to devices that are 510(k)-exempt or require premarket  
165 approval (PMA).  
166

167 This draft guidance specifically addresses software modifications. Any modifications that are  
168 not modifications to software are not within the scope of this draft guidance; such changes (e.g.,  
169 labeling changes) should be evaluated using [Deciding When to Submit a 510\(k\) for a Change to  
170 an Existing Device \(K97-1\)](#). This draft guidance does not apply to software for which the  
171 Agency has stated in guidance that it does not intend to enforce compliance with applicable  
172 regulatory controls (see, e.g., [Mobile Medical Applications Guidance for Industry and FDA  
173 Staff](#)). Further, this draft guidance does not address the software lifecycle (covered in  
174 AAMI/ANSI/IEC 62304: *Medical device software - software life cycle processes*), what  
175 documentation should be included in a 510(k) for a software modification (covered in [Guidance  
176 for the Content of Premarket Submissions for Software Contained in Medical Devices](#)) or the  
177 principles that are applicable to the validation of medical device software (covered in [General  
178 Principles of Software Validation; Final Guidance for Industry and FDA Staff](#)).  
179

180 This guidance, when finalized, is also intended to apply to situations when a legally-marketed  
181 existing device is the subject of a recall and a change in the device or its labeling is indicated.  
182 For more information on recommended procedures in a recall situation, please see Blue Book

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<sup>1</sup> IMDRF/SaMD WG/N10: [Software as a Medical Device \(SaMD\): Key Definitions](#).

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183 Memorandum K95-1, [510\(k\) Requirements During Firm-Initiated Recalls](#). As stated in that  
184 guidance, if a correction alters a device rather than simply restoring it to its original  
185 specifications, a new 510(k) may be required. This guidance, when finalized, may be useful in  
186 determining whether a new 510(k) is warranted in cases where the correction does alter the  
187 device.

188

189 This draft guidance does not specifically address combination products, such as drug/device or  
190 biologic/device combinations; however, the general principles and concepts described herein  
191 may be helpful to manufacturers in determining whether a 510(k) is necessary for changes to  
192 software-containing device constituent parts of combination products.

193

194 Software modifications can take numerous forms, including, but not limited to, the following:

195

- 196 • Adaptive – modification of software to keep it usable in a changed or changing  
197 environment;
- 198 • Corrective – reactive modification of software to address discovered faults; or
- 199 • Perfective – modification of software to improve performance or maintainability.

200

201 In addition, software modifications may be identified by many other names, including, but not  
202 limited to: bug fix, hot patch, software change or tweak. Regardless of name or form, these are  
203 considered design changes under the Quality System regulation, 21 CFR Part 820.

204

205 This draft guidance, when finalized, is not intended to supersede device-specific guidance (such  
206 as the [Infusion Pumps Total Product Life Cycle](#)), but may cover areas not addressed in any  
207 device-specific guidance.

208

209 Since the scope of this draft guidance is limited to changes to software only, it may be necessary  
210 to refer to other relevant FDA guidance documents that aid in the evaluation of non-software  
211 device modifications, such as [Deciding When to Submit a 510\(k\) for a Change to an Existing  
212 Device \(K97-1\)](#). It is the manufacturer's responsibility to collectively evaluate the combination  
213 of both software and non-software changes to evaluate the impact of a change to a device. For  
214 those circumstances where the proposed change is not addressed in this draft guidance, in  
215 [Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](#), or in a device-  
216 specific guidance, manufacturers are encouraged to contact the appropriate office in CDRH or  
217 CBER.

218

## **IV. Guiding Principles**

219

220  
221 In using this guidance for deciding whether to submit a new 510(k) for a modification to an  
222 existing- device, a number of guiding principles should be followed. Some derive from existing  
223 FDA 510(k) policy and are widely known, and others are necessary for using the logic scheme  
224 contained in this guidance. Thus, anyone using this guidance should bear in mind the following  
225 guiding principles:

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- 270
- **Modifications made with intent to significantly affect safety or effectiveness of a device** – If a manufacturer modifies their device with the intent to significantly improve the safety or effectiveness of the device (for example, in response to a known risk, adverse events, etc.), a new 510(k) is likely required. Changes that are not intended to significantly affect the safety or effectiveness of a device, however, should still be evaluated to determine whether the change could significantly affect device safety or effectiveness.
    - If a manufacturer modifies their device to address a violation or recall, they should refer to FDA guidances Blue Book Memorandum K95-1, [\*510\(k\) Requirements During Firm-Initiated Recalls\*](#) and [\*Distinguishing Medical Device Recalls from Medical Device Enhancements\*](#).
  - **“Could significantly affect” evaluation and the role of testing** – To determine whether a change or modification could significantly affect the safety or effectiveness of a device, the manufacturer should first conduct a risk-based assessment, using the guidance below, of whether the change could significantly affect the device’s safety or effectiveness, either positively or negatively. This risk-based assessment should identify and analyze all new risks and changes in known risks resulting from the device modification, and lead to an initial decision whether or not a new 510(k) is required. If the initial decision following the risk assessment is that a new 510(k) is not required, this decision should be confirmed by successful, routine verification and validation activities. If routine verification and validation activities produce any unexpected issues, any prior decision that a new 510(k) is not required should be reconsidered. Verification and validation requirements apply for all devices subject to 21 CFR 820.30.
  - **Unintended consequences of changes** – Software modifications may trigger additional unintended or unplanned consequences. In evaluating whether a change requires a new 510(k), manufacturers should consider whether there are any unintended consequences or effects of the device change. For example, an intended operating system (OS) upgrade may trigger unintended effects in device drivers and software code embedded in the device. Manufacturers should consider all consequences of changes to determine whether a new 510(k) is required.
  - **Use of risk management** – The risk profile referred to throughout this document is based on the combination of multiple risk concepts which are important for managing the risks of medical devices. Hazards and hazardous situations, risk estimation, risk acceptability, risk control, risk/benefit analysis and overall risk evaluation are all concepts that can be applied during the design and development of a medical device. The concept of risk, as defined in ISO 14971: *Medical devices – Application of risk management to medical devices*, is the combination of the probability of occurrence of harm and the severity of that harm. Although the risk terminology used in this document is primarily derived from ISO 14971, it is recognized that an individual manufacturer’s terminology may differ. Because 21 CFR 807.81(a)(3)(i) requires a new 510(k) when a change “could



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- 271 significantly affect safety or effectiveness,” both safety and effectiveness should be  
272 considered in evaluating a device’s risk profile. The risk terminology from AAMI TIR  
273 32 “Medical Device Software Risk Management” is also used in this guidance.  
274
- 275 • **Evaluating simultaneous changes** – Because many simultaneous changes may be  
276 considered at once, each change should be assessed separately, as well as in aggregate.  
277
  - 278 • **Appropriate comparative device and cumulative effect of changes** – In using this  
279 guidance to help determine whether a particular change requires the submission of a new  
280 510(k), manufacturers should make a risk-based assessment that compares the changed  
281 device to their device as previously found to be substantially equivalent in their most  
282 recently cleared 510(k) (or to their preamendments device, if no 510(k) has been cleared).  
283 Manufacturers may make a number of changes without having to submit a new 510(k),  
284 but each time they make a change, the device they should compare it to is their most  
285 recently cleared device. When the manufacturer compares the proposed modified device  
286 to the device in its most recently cleared 510(k), the manufacturer should evaluate the  
287 cumulative impact of all changes since their most recently cleared 510(k).  
288
  - 289 • **Documentation requirement** – Whenever manufacturers change their device, they must  
290 take certain actions to comply with the QS regulation, 21 CFR Part 820, unless the device  
291 in question is exempt by regulation from the QS regulation. The QS regulation requires,  
292 among other things, that device changes be documented.  
293
  - 294 • **510(k) submissions for modified devices** – When a new 510(k) is submitted for a device  
295 with multiple modifications, that 510(k) should describe all changes that trigger the  
296 requirement for a new 510(k). That 510(k) should also describe other modifications since  
297 the last cleared 510(k) (i.e., those that did not require a new 510(k)) that would have been  
298 documented as part of the original 510(k) for that device. This helps ensure that FDA has  
299 a more complete understanding of the device under review. For instance, an original  
300 510(k) would not typically identify or describe individual components of a circuit board,  
301 such as resistors, and therefore FDA would not expect modifications to the resistors to be  
302 listed in the new 510(k) for a modified device if they did not trigger the requirement for a  
303 510(k). However, 510(k)s typically include a listing of device warnings in the labeling, so  
304 if a warning in the device’s labeling has been modified, that change should be described  
305 in the new 510(k) even if that change did not itself trigger the requirement for a new  
306 510(k).  
307
    - 308 ○ If a manufacturer makes multiple changes to a device, but only one change  
309 triggers the requirement for a new 510(k), the changes that do not require a new  
310 510(k) may be immediately implemented, so long as those changes can be  
311 implemented independently of changes that do require a new 510(k). Those  
312 changes should, however, be described in the new 510(k) for the change that does  
313 require submission (subject to the preceding bullet).
- 314

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- 315 • **Substantial equivalence determinations** – Manufacturers should understand that, even  
316 though they may follow this guidance and submit a new 510(k), a substantially equivalent  
317 determination is not assured. See [The 510\(k\) Program: Evaluating Substantial](#)  
318 [Equivalence in Premarket Notifications \(510\(k\)\)](#) for more information on the decision-  
319 making process FDA uses to determine substantial equivalence.  
320

## 321 **V. How to Use This Guidance**

322  
323 This guidance uses a flowchart and text with considerations and examples to help manufacturers  
324 through the logic scheme necessary to decide whether to submit a new 510(k) for a software  
325 change to an existing device.  
326

327 A single logic scheme covering all the intricacies in software modifications and their impact on  
328 the decision to submit a new 510(k) would be impractical to develop. Rather, for ease of use, a  
329 flowchart and text expected to cover the most common software modifications has been created.  
330

331 **Manufacturers should use the flowchart in concert with the guiding principles above, the**  
332 **text below, and additional factors in section VI.** Answer the questions posed for each  
333 individual type of change (e.g., performance specification change, OS driver change) until a  
334 decision is made either to submit a new 510(k) or to document the basis for concluding that a  
335 new 510(k) is not required. As mentioned above, when making the decision on whether to  
336 submit a new 510(k) for changes, the manufacturer’s basis for comparison of any changed device  
337 should be the device described in the manufacturer’s most recently cleared 510(k) for this  
338 device, or to their legally-marketed preamendments device. Manufacturers are required to submit  
339 a new 510(k) when a change (or changes) exceeds the §807.81(a)(3) threshold, "could  
340 significantly affect the safety or effectiveness of the device," or constitutes a “major change or  
341 modification in the intended use of the device.” This significant effect could be positive or  
342 negative. One must keep in mind that what may on the surface appear to be one discrete change  
343 to a device may involve multiple changes of various types.  
344

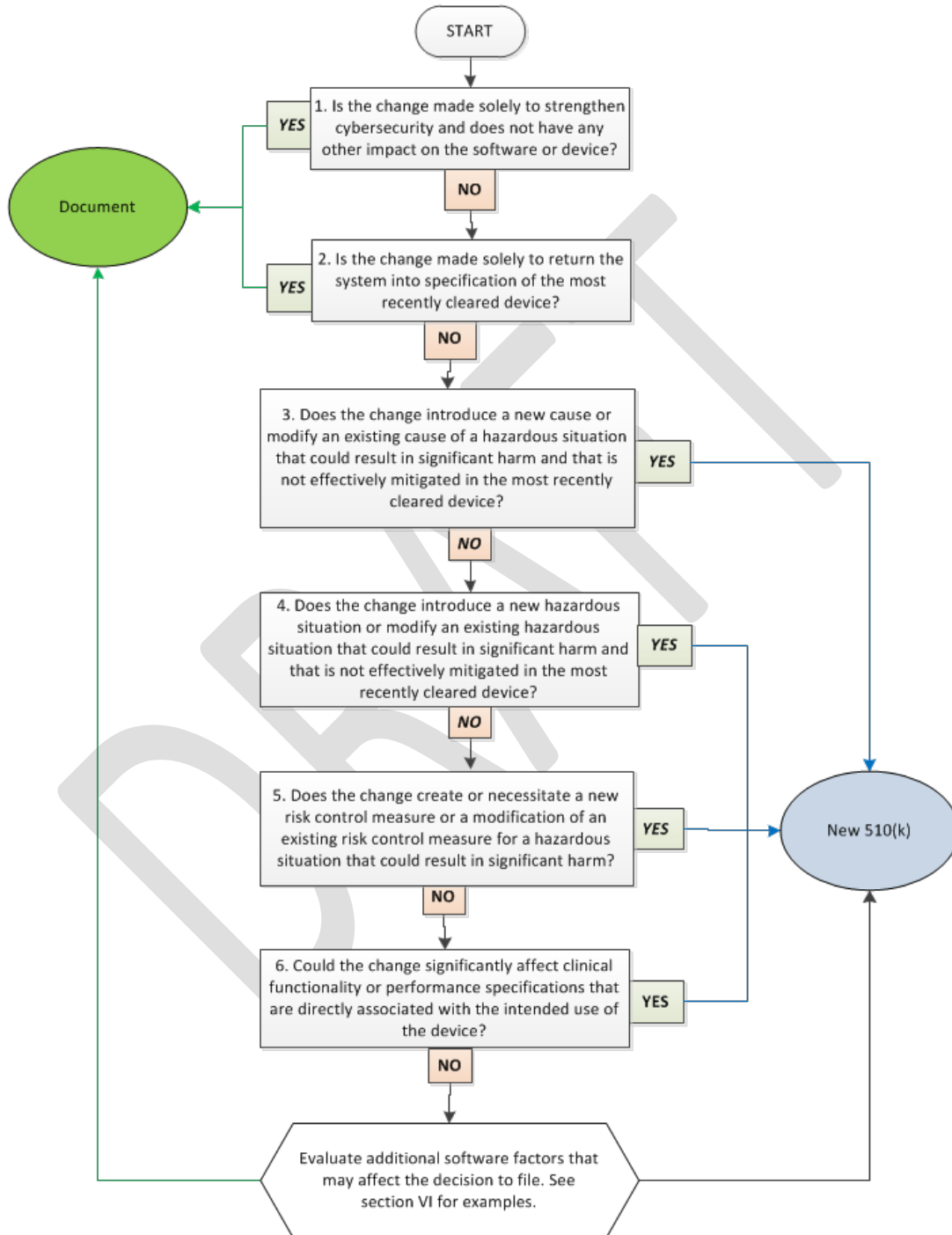
345 **In cases with multiple changes, manufacturers should use all applicable parts of the**  
346 **flowchart and explanatory text.** As explained in the Guiding Principles, a new 510(k) is  
347 required for any change that triggers the need for a new 510(k).  
348

349 Note that the flowchart entries, “new 510(k)” and “documentation,” are written in this way only  
350 for conciseness. The reader should interpret “new 510(k)” as **a new 510(k) is likely required**  
351 and “document” as **a new 510(k) is likely not required, document your analysis, and file it**  
352 **for future reference.** The goal of the flowchart is to provide guidance in answering a  
353 manufacturer’s questions on whether a new 510(k) should be expected for a software change and  
354 to minimize the number of instances where the answer would be uncertain.  
355  
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359 Figure 1 – When to File a New 510(k) For a Software Change to an Existing Device  
360



361

362

363

364 **1. Is the change made solely to strengthen cybersecurity and does**  
365 **not have any other impact on the software or device?**

366

367 In many cases, a change made solely to strengthen cybersecurity is not likely to require a new  
368 510(k). Cybersecurity updates are considered a subset of software changes that are implemented  
369 to strengthen the security of a system, protect information, and reduce disruption in service.  
370 FDA expects manufacturers to ensure that such changes do not impact the performance of the  
371 device by performing necessary analysis, verification and/or validation. If a manufacturer  
372 becomes aware of any incidental or unintended impacts of the change on other aspects of the  
373 software or device, the manufacturer should continue through the remaining questions in this  
374 guidance. The manufacturer should also refer to FDA's [Content of Premarket Submissions for](#)  
375 [Management of Cybersecurity in Medical Devices](#).

376

377 **2. Is the change made solely to return the system into**  
378 **specification of the most recently cleared device?**

379

380 When a change to the software only restores the device to the specifications of the most recently  
381 cleared device, then a new 510(k) is likely not required. Generally, it is unlikely that  
382 modifications to software solely to restore the device to the most recently cleared device's  
383 specifications could significantly impact safety, effectiveness, or intended use of the device;  
384 however, manufacturers should evaluate the impact of the software changes. Manufacturers  
385 should conduct an analysis that involves determining the overall impact of the change to the  
386 device in terms of risk assessment and performance. The concepts expressed in Questions 3  
387 through 6 below could be helpful in this analysis. In addition, this analysis is important for  
388 evaluating any modification that adds new features in order to restore the device to its original  
389 specifications.

390

391 Missing, incomplete, ambiguous, or conflicting software requirements may lead to a software  
392 modification that involves updating specifications, resulting in additional software code changes.  
393 In these situations, the answer to this question is likely no and the manufacturer should proceed  
394 to Question 3.

395

396 Generally, manufacturers are not required to submit a new 510(k) for changes to a specification  
397 document for the purpose of clarifying an existing software requirement or to capture a missing  
398 software requirement, provided that this does not necessitate any changes to software code or  
399 product performance specifications. However, manufacturers should still assess the impact of  
400 the changes on other software documentation when applying appropriate design controls.

401

402 **3. Does the change introduce a new cause or modify an existing**  
403 **cause of a hazardous situation that could result in significant**

404 **harm and that is not effectively mitigated in the most recently**  
405 **cleared device?**

406 A “hazardous situation” exists when there is a potential source of harm; that is, there is  
407 potential exposure to physical injury or damage to the health of people. The term “cause” refers  
408 to the cause of a hazardous situation, as identified and defined by the manufacturer in the risk  
409 management file for the device. Significant harm refers to situations where the risk level is  
410 serious or more severe, e.g., the risk could result in injury or impairment requiring professional  
411 medical intervention, permanent impairment, or death.

412

413 The purpose of this question is to determine whether a new *cause* of a hazardous situation is  
414 created, or an existing cause altered, as a result of the software change. If the following criteria  
415 are all met, then a new 510(k) is likely required:

416

417 1. The change leads the manufacturer to document a new cause or the modification of an  
418 existing cause in the risk management file.

419 • Note: This criterion is met if the change creates a new cause or modifies an  
420 existing cause (such as increasing the likelihood) of an existing hazardous  
421 situation.

422 2. The level of harm associated with the new or modified cause is considered serious or  
423 more severe, e.g., the cause of the hazardous situation could result in injury or  
424 impairment requiring professional medical intervention, permanent impairment or  
425 death. For the purposes of this criterion, the pre-mitigation risk score should be  
426 assessed in order to focus on the effects of the change.

427 3. The hazardous situation associated with the new or modified cause is not already  
428 effectively mitigated in the most recently cleared device.

429 • Note: This criterion is met if there are no existing risk control measures in the  
430 most recently cleared device that reduce the risk associated with this cause to an  
431 acceptable level.

432

433 If all of the criteria are not met, proceed to Question 4.

434

435 **4. Does the change introduce a new hazardous situation or**  
436 **modify an existing hazardous situation that could result in**  
437 **significant harm and that is not effectively mitigated in the**  
438 **most recently cleared device?**

439

440 The purpose of this question is to determine whether a new *hazardous situation* is created, or an  
441 existing hazardous situation altered, as a result of the software change. If the following criteria  
442 are all met, then a new 510(k) is likely required:

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- 443 1. The change leads the manufacturer to document a new hazardous situation or the  
444 modification of an existing hazardous situation in the risk management file.  
445 • Note: This criterion is met if the change creates a new hazardous situation or  
446 modifies an existing hazardous situation (such as increasing the likelihood of  
447 such).
- 448 2. The level of harm associated with the new or modified hazardous situation is considered  
449 serious or more severe, e.g., the hazardous situation could result in injury or impairment  
450 requiring professional medical intervention, permanent impairment or death. For the  
451 purposes of this criterion, the pre-mitigation risk score should be assessed in order to  
452 focus on the effects of the change.
- 453 3. The hazardous situation is not effectively mitigated in the most recently cleared device.  
454 • Note: This criterion is met if there are no existing risk control measures in the  
455 most recently cleared device that reduce the risk associated with this hazardous  
456 situation to an acceptable level.  
457

458 If all of the criteria are not met, proceed to Question 5.

459

460 **5. Does the change create or necessitate a new risk control**  
461 **measure or a modification of an existing risk control measure**  
462 **for a hazardous situation that could result in significant harm?**  
463

464 It is possible that introducing new risk control measures or implementing changes to risk control  
465 measures could significantly affect the safety or effectiveness of the product, and thus such  
466 changes should be evaluated. It may be that the change is directly tied to the risk control  
467 measures or the software change may necessitate a new or modified risk control measure.  
468 Changes to risk control measures may be necessary due to new, modified, or previously  
469 unknown hazardous situations or causes thereof. If the changes to risk controls are necessary to  
470 effectively prevent significant harm, a new 510(k) is likely required. Note that a new 510(k) is  
471 likely not required as a result of a manufacturer implementing additional risk control measures,  
472 provided this is not in response to a new, modified, or previously known hazardous situation or  
473 causes thereof. For example, a new 510(k) is likely not required when implementing redundant  
474 risk control measures or enhancing existing risk control measures if the risk control measures in  
475 the most recently cleared device effectively mitigated the hazardous situation.  
476

477 If the answer to this question is no, proceed to Question 6.  
478

479 **6. Could the change significantly affect clinical functionality or**  
480 **performance specifications that are directly associated with the**  
481 **intended use of the device?**  
482

483 Changes in performance specifications encompass everything from routine specification changes  
484 necessary to improve device performance to significant product redesigns. For the purpose of  
485 this question, specifications include elements that could influence the device’s ability to  
486 clinically perform as intended. These specifications may address attributes such as speed,  
487 strength, response times, throughput, limits of operation, reliability, delivery rate, or assay  
488 performance.

489  
490 If the software change could significantly affect clinical functionality or performance  
491 specifications that are directly associated with the intended use of the device, then a new 510(k)  
492 is likely required. For *in vitro* diagnostic devices (IVDs), this includes a change that could have  
493 clinically significant impact in terms of clinical decision-making. This question does not address  
494 direct changes to the intended use of the device. If there is a change in the intended use of the  
495 device, refer to FDA’s guidance, [Deciding When to Submit a 510\(k\) for a Change to an Existing](#)  
496 [Device \(K97-1\)](#) .  
497

498 Performance specifications for IVDs establish clinical and analytical performance specifications  
499 as part of the design input for the device. Assay performance includes both clinical and  
500 analytical performance. Clinical performance is the documented ability of an IVD test or test  
501 system to identify, measure, monitor, or predict the presence or absence of, or the future  
502 development of, a clinical condition or predisposition, for which the device is intended.  
503 Analytical performance refers to the documented ability of an IVD test or test system to measure  
504 or detect a target analyte or substance that the IVD test or test system is represented or purported  
505 to identify or measure. Depending on the assay, analytical performance specifications may  
506 include, for example:

- 507  
508
  - Analytical Sensitivity: limit of detection, reactivity (inclusivity)
  - Analytical Specificity: exclusivity, cross-reactivity, interference
  - Cut-off and equivocal zone
  - Precision: site-to-site reproducibility, within-laboratory precision/repeatability  
512

513 There are also times when IVD functionality could be changed but the change is not related to  
514 the IVD’s intended use and the performance of the modified device could not significantly  
515 change from previously cleared performance claims. For these types of software changes, a new  
516 510(k) is likely not required.

517  
518

519 **VI. Additional Factors to Consider When Determining**  
520 **When to Submit a New 510(k) for a Software Change to**  
521 **an Existing Device**

522

523 **In addition to the questions above, the common issues below should also be considered**  
524 **when determining if a new 510(k) is required.**

525

526 Medical device software is used in a wide variety of applications and is subject to a wide variety  
527 of changes. This draft guidance, therefore, cannot address every type of software change.  
528 Nonetheless, the questions in the flowchart and the associated recommendations in the text  
529 provide a guide for manufacturers' decision-making and associated documentation. The goal of  
530 the draft guidance is to provide examples of software changes that clearly could have a  
531 significant impact on the safety or effectiveness of the device based on functional changes to the  
532 device's operation (Note: modifications in the intended use of the device are covered in [Deciding](#)  
533 [When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](#)). The impact of software  
534 changes on safety and effectiveness may not always be clear. This is often the case when  
535 making general code changes to software that are not necessarily intended to change function,  
536 but rather to perform what could be described as "code maintenance" or "infrastructure"  
537 modifications. These types of changes can, if not controlled properly, create unexpected changes  
538 to how the device functions. As such, these types of changes, as well as others described in this  
539 section, should involve a careful evaluation of their potential impact on device safety and  
540 effectiveness.

541

542 In addition to change management, these types of changes should also involve careful  
543 consideration of the overall architecture of the software. If the software architecture was  
544 developed in a planned, modular format, the likelihood of unintended impact to other areas of the  
545 code may be significantly reduced. On the other hand, if the software code was developed in a  
546 looser construct, without a clear architectural plan, the ability to clearly delineate between  
547 functional modules in the code may be reduced. The potential impact to device safety and  
548 effectiveness increases in code with looser construct, due to the inherent risk of unintended  
549 changes in code without clear boundaries in the functional modules.

550

551 The purpose of this section is to provide guidance regarding evaluation of certain types of  
552 software changes, such as "code maintenance" and "infrastructure" changes. Manufacturers are  
553 encouraged to discuss these "gray areas" with the relevant CDRH or CBER Office and Branch if  
554 there are questions about whether to submit a new 510(k) for these or other types of software  
555 changes. In most cases, this will be the Branch under which the device was originally cleared.

556

557 **Common Software Change Types**

558

559 The following list of common change types are intended to help manufacturers consider  
560 additional factors that may affect a decision to submit a new 510(k). Note that this list is not



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561 exhaustive and any questions should be discussed with the respective CDRH Offices and/or  
562 CBER Offices and/or Branches responsible for the device being modified.

563

564 Some of the common software change types include:

565

- 566 • **“Infrastructure”** changes are modifications made to the software support system.  
567 Examples include but are not limited to: switching compilers, changing languages (C to  
568 C++, C++ to Java), or changing software drivers or libraries.

569

570 The complexity of the change should be taken into consideration while determining  
571 whether the change requires a new 510(k). For example, when changing programming  
572 languages, the similarity of the programming syntax between the two languages, as well  
573 as other factors (such as the coding paradigm associated with the old and new code),  
574 should be considered. A change from C to C++ may not entail significant code writing if  
575 the syntax is similar. On the other hand, moving from a functional or logical coding  
576 paradigm to an Object Oriented Programming paradigm, in conjunction with the change  
577 from C to C++, could involve significant software re-write, and a new 510(k) is likely  
578 required.

579

580 Similar analysis generally applies to software driver changes, OS changes, etc. It should  
581 be noted that significant changes to verification and validation scripts might be a signal  
582 that significant infrastructure changes have taken place and should be examined. Updates  
583 to scripts alone do not indicate a new 510(k) is required; however, it is important to  
584 understand why the scripts are being updated.

585

- 586 • **“Architecture”** changes are modifications to the overall structure of the software.  
587 Examples include but are not limited to: porting to a new OS, software changes to  
588 support a new hardware platform, and new middleware.

589

590 These changes may impact the overall performance of the device or extend the  
591 environment in which the device can operate. The extent of the changes and the impact  
592 that they have on the device should be considered in determining whether a new 510(k) is  
593 required.

594

- 595 • **“Core algorithm”** changes are modifications made to an algorithm that directly drive the  
596 device’s intended use. Examples include: alarm algorithms on a monitor, a motor control  
597 algorithm for an infusion pump, and a detection module and measurement engine  
598 algorithm for an IVD.

599

600 Changes to the core algorithm that impact performance are addressed by the preceding  
601 section and flowchart. However, it is important to understand that a complete rewrite of  
602 the algorithm, even with the same performance claims and risk profile, may be significant  
603 enough to require a new 510(k) because the rewrite may impact performance indirectly.

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- 631
- **“Clarification of Requirements – No change to Functionality”** are changes made to clarify software requirements after a product has received premarket clearance. This clarification may be revised phrasing of an existing requirement or creation of a new requirement altogether, without changing or adding functionality. Changes made to clarify the requirements as discussed here likely do not require a new 510(k).
  - **“Cosmetic Changes – No change to Functionality”** are changes made to the appearance of the device that do not impact the clinical use of the device. For example, changing the company logo that is displayed on the background of every screen could involve modifying multiple software modules; while the number of modules impacted may be large, it is unlikely that the intended change could impact the device’s safety and effectiveness or intended use, and a new 510(k) is likely not required.
  - **“Reengineering” and “refactoring”** are two common software maintenance techniques. “Reengineering” is defined as the examination and alteration of software to reconstitute it in a new form, and includes the subsequent implementation of the new form. It is often undertaken to replace aging legacy software. “Refactoring” is a disciplined technique for restructuring a software program’s internal structure without changing its clinical performance specification. Refactoring seeks to improve a program structure and its maintainability. In general, reengineering often results in broader and more complex changes, while refactoring is often narrower in scope and less complex. The complexity of the change should be considered to determine whether the change requires a new 510(k). Changes that are minor modifications to enhance the maintainability of the device within its specification context are unlikely to require a new 510(k). Changes involving significant software re-write likely require a new 510(k) because of the impact on the performance and on the risk controls.

632 **Appendix A. Software Modification Examples**

633

634 The following are hypothetical examples of software changes with explanations as to why they  
635 likely would or would not require a new 510(k). Note that these generalized examples do not  
636 necessarily account for every possible detail, risk, or consideration a manufacturer should  
637 evaluate, and should not be taken to mean that the changes described definitely do or do not  
638 require a new 510(k). Real-world device modification decisions will depend on the particular  
639 details of the change and the specific device in question. Also note that devices with changes  
640 requiring a new 510(k) may not be commercially distributed before FDA clears the changed  
641 device. See 21 CFR 807.100(a) and sections 513(f)(1) and 513(i) of the Act.

642

643 The examples below are only intended to illustrate the principles and recommendations  
644 discussed above with regard to a particular question. As such, the examples each contain only  
645 the response to the question that is being highlighted; this does not necessarily mean that an  
646 earlier question would not have appropriately led to a decision to submit a new 510(k).

647

<b>Example Number</b>	<b>Flowchart Question</b>	<b>Title</b>
1.1	Q1	<b>Proactive software security patch</b>
1.2	Q1	<b>Adding encryption and additional access control for remote users</b>
2.1	Q2	<b>Modify system to meet specification</b>
2.2	Q2	<b>Correcting DICOM retrieve parameter error</b>
2.3	Q2	<b>Error during maintenance procedure</b>
2.4	Q2	<b>Data error</b>
2.5	Q2	<b>Database error</b>
3.1	Q3	<b>Adding a new diagnostic parameter</b>
3.2	Q3	<b>Removing a diagnostic parameter</b>
4.1	Q4	<b>Customer maintenance procedure</b>
4.2	Q4	<b>Adding new programming mode to a cardiac monitor</b>
4.3	Q4	<b>Imaging catheters – new optical module and new laser</b>
5.1	Q5	<b>Modification of a risk control</b>
5.2	Q5	<b>Modification of threshold settings</b>

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5.3	Q5	<b>Adding user interface alerts and controls</b>
5.4	Q5	<b>Print patient information on PACS report</b>
5.5	Q5	<b>Infusion pump alarm</b>
6.1	Q6	<b>Improve sample throughput 1</b>
6.2	Q6	<b>Improve sample throughput 2</b>
6.3	Q6	<b>Analyzer remote monitoring feature improvement</b>
6.4	Q6	<b>Software change to modify summary window</b>
6.5	Q6	<b>OEM module</b>
6.6	Q6	<b>Home monitor</b>
6.7	Q6	<b>Device reprocessor user interface change</b>
6.8	Q6	<b>Modify device algorithms</b>
6.9	Q6	<b>Modification to alarm duration</b>

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649 **1. Flowchart Question 1 Examples**

650

651 **1.1. Proactive software security patch**

652

653 **Description:** A device manufacturer finds a security vulnerability as part of an ongoing  
654 security evaluation of their device. The manufacturer modifies the software solely to  
655 remove this vulnerability. The manufacturer’s analysis determined that the change does  
656 not have any other impact on the software or the device.

657

#	Question	Yes/No	Rationale
1	Is the change made solely to strengthen cybersecurity and does not have any other impact on the software or device?	Yes	The change is made solely to address cybersecurity vulnerabilities or to strengthen cybersecurity. The manufacturer’s analysis determined that the change does not impact any other aspects of the software or device.

658

659 **Outcome:** Document the change to file.

660

661 **1.2. Adding encryption and additional access control for remote users**

662

663 **Description:** A manufacturer makes a software modification to add encryption to the  
664 configuration file of the device, and add passcode requirements for remote users, in  
665 addition to the password needed to access the device. A timeout is also added for remote  
666 users. The manufacturer’s analysis determined that the change does not have any other  
667 impact on the software or the device.

668

#	Question	Yes/No	Rationale
1	Is the change made solely to strengthen cybersecurity and does not have any other impact on the software or device?	Yes	The change is made to restrict user/customer access to appropriate levels and provide protection to the device configuration information, in order to strengthen the cybersecurity of the device. The manufacturer’s analysis determined that the change does not have any other impact on the software or the device.

669

670 **Outcome:** Document the change to file.

671

672 **2. Flowchart Question 2 Examples**

673

674 **2.1. Modify system to meet specification**

675

676 **Description:** A manufacturer makes a software modification to prevent system software  
677 from truncating Specimen Identification barcode information. Without the change, the  
678 software system would truncate the Specimen ID from the point of an inserted invalid  
679 character. For instance, if the invalid character was “%” and the Barcode Specimen ID  
680 was “12345%678”, the system software would read and assign a Specimen ID of

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681 “12345.” This defect could lead to mis-association of patient data. Incorrect software  
682 collation of patient information with patient results could lead to incorrect reports. The  
683 specification of the most recently cleared device indicated what constituted an invalid  
684 character and how invalid characters were to be handled. However, the software did not  
685 handle this one particular invalid character in line with the specification. A change is  
686 made to the software to prevent the truncation of Specimen Identification barcode  
687 information where an invalid character has been inserted.  
688

#	Question	Yes/No	Rationale
2	<b>Is the change made solely to return the system into specification of the most recently cleared device?</b>	Yes	The software change disallowed use of the specific invalid character in Specimen IDs as defined in the instrument host interface specification. The original specification indicated how all illegal characters were to be handled. The original device handled all but one as indicated in the specification. The change is made solely to ensure the software meets the original specification.

689 **Outcome:** Document the change to file.  
690

691  
692 **2.2. Correcting DICOM retrieve parameter error**  
693

694 **Description:** A PACS (Picture Archiving and Communication System) is able to  
695 automatically retrieve prior studies from a radiology information system to allow  
696 comparison with the current study. A software error resulted in a non DICOM-compliant  
697 (Digital Imaging and Communications in Medicine standard; <http://dicom.nema.org/>)  
698 sending of query parameters that prevented the automatic fetching of prior studies. A  
699 manual workaround existed, allowing the user to open these prior studies as needed. The  
700 manufacturer implements a software change to bring the product back to specification  
701 regarding DICOM conformance (send and retrieve.)  
702

#	Question	Yes/No	Rationale
2	<b>Is the change made solely to return the system into specification of the most recently cleared device?</b>	Yes	The software change is implemented solely to return the system into specification of the most recently cleared device regarding DICOM conformance (send and retrieve) by automatically opening prior studies as expected in a routing reading workflow.

703 **Outcome:** Document the change to file.  
704

705  
706 **2.3. Error during maintenance procedure**  
707

708 **Description:** A manufacturer makes a software modification to fix an automated  
709 scheduled daily maintenance procedure. The defect concerned the cleaning solution  
710 bottle size parameter used in a maintenance procedure. The defect impacted the system’s  
711 ability to detect fluid on the bottle septum and caused intermittent fluid detection errors

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712 during the maintenance procedure. The user may need to repeat the procedure 2-3 times  
713 to complete the procedure without error. A software change is made to update the size  
714 parameter as was originally documented in the software specifications.  
715

#	Question	Yes/No	Rationale
2	Is the change made solely to return the system into specification of the most recently cleared device?	Yes	The change is to correct the software error to change the bottle size parameter back to the specified bottle size to bring system back into specification.

716  
717 **Outcome:** Document the change to file.

718  
719 **2.4. Data error**

720  
721 **Description:** An issue was observed in IVD analyzer software that collects reagent  
722 administrative records (e.g., material number, lot number, expiration date). The records  
723 are to be written by the software into a database table. After enough records are collected  
724 to fill the table, newly-collected records are then to be written in the first row of the table,  
725 overwriting previous records. Because of a software bug, the system mistakenly merges  
726 the new data with the existing data in the first row of the table. The cause of the anomaly  
727 was determined to be a coding error that did not affect any of the software requirements.  
728 A change was made to correct the software code in the control unit of the analyzer to  
729 ensure that data written to a row in the table is not merged with any existing data. The  
730 change to the software involved modification of a table within the analyzer software to  
731 add new columns to track the administrative data stored for reagents to prevent data from  
732 being merged.  
733

#	Question	Yes/No	Rationale
2	Is the change made solely to return the system into specification of the most recently cleared device?	Yes	The change was only to address a software anomaly and was not a change in specification or functionality of the most recently cleared device.

734  
735 **Outcome:** Document the change to file.

736  
737 **2.5. Database error**

738  
739 **Description:** An issue was observed for an IVD analyzer in the field. The IVD analyzer  
740 software collects reagent administrative records (e.g., material number, lot number,  
741 expiration date). The records are to be written by the software into a database table. After  
742 enough records are collected to fill the table, newly-collected records are then to be  
743 written in the first row of the table, overwriting previous records. Under certain  
744 conditions, the software system mistakenly merges the new data with the existing data in

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745 the first row of the table in the database, which may lead to an incorrect result. The cause  
746 of the bug was found to be an incorrectly worded software requirement that led to an  
747 error in the software code. The requirement was rewritten. An additional software  
748 change was made to correct the software code in the control unit of the analyzer. Code  
749 was modified to ensure that data written to a database is not merged with any existing  
750 data. The change to the software involved creating an entirely separate database within  
751 the instrument software, specifically for the administrative records stored for reagents to  
752 prevent records from being merged. This change required a specification change at the  
753 unit level to describe the new database.  
754

#	Question	Yes/No	Rationale
2	<b>Is the change made solely to return the system into specification of the most recently cleared device?</b>	No	A change was made to correct a coding error by adding a new database. This caused a change to the design specifications of the software.

755  
756 **Outcome:** Continue to question 3.

757  
758 **3. Flowchart Question 3 Examples**

759  
760 **3.1. Adding a new diagnostic parameter**

761  
762 **Description:** An electroencephalogram (EEG) diagnostic monitor was cleared with  
763 spectral edge frequency (SEF) and peak power (PP) as quantitative parameters. The  
764 device's intended use is to monitor brain electrical activity through electrodes placed on  
765 the surface of the head. A software modification is made to add Amplitude Integrated  
766 EEG (aEEG) as an additional quantitative parameter that was not included in the original  
767 premarket notification.  
768

#	Question	Yes/No	Rationale
3	<b>Does the change introduce a new cause or modify an existing cause of a hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?</b>	Yes	The hazardous situation most commonly associated with quantitative diagnostic parameters is the risk of incorrect or confusing information to the physician leading to a misdiagnosis which could result in significant harm. While the causes of incorrect information for SEF and PP would be included in the original risk files, aEEG introduces a new cause related to an error in the aEEG calculation. A new 510(k) is required because the new cause is not effectively mitigated in the most recently cleared device and the hazardous situation, as discussed above, could result in significant harm.

769  
770 **Outcome:** Submit the change in a new 510(k).

771  
772 **3.2. Removing a diagnostic parameter**



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778

**Description:** An EEG diagnostic monitor was cleared with SEF and PP as quantitative parameters. The device’s intended use is to monitor brain electrical activity through electrodes placed on the surface of the head. A modification is made to remove PP from the displayed quantitative parameters based on lack of need from marketing.

#	Question	Yes/No	Rationale
3	<b>Does the change introduce a new cause or modify an existing cause of a hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?</b>	No	Removal of PP does not introduce a new cause of a hazardous situation or change an existing cause of a hazardous situation that is not effectively mitigated.

779  
780  
781

**Outcome:** Continue to question 4.

782 **4. Flowchart Question 4 Examples**

783

784 **4.1. Customer maintenance procedure**

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**Description:** The manufacturer makes a software modification to prevent a patient sample probe motor from overheating during a customer maintenance procedure. Power is applied to the sample probe motor to keep the sample probe assembly in a locked position during the user maintenance procedure. In the field, it was reported that applying power to the sample probe motor for more than 20 minutes causes the motor to overheat and creates a potential minor burn hazard (i.e., it becomes too hot to touch safely). The software change applies a timeout to power being applied to the sample probe motor during the maintenance procedure; after 10 minutes, power to the sample probe motor is turned off. An additional software change adds a message window at the beginning of the procedure to alert the user that the procedure must be completed within a 10-minute window or the system will cut power to the motor. A limit of 10 minutes was determined to keep the motor from overheating to the point of creating a potential minor burn hazard.

#	Question	Yes/No	Rationale
4	<b>Does the change introduce a new hazardous situation or modify an existing hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?</b>	No	The change provides mitigation to an existing hazardous situation that was not appropriately mitigated in the cleared device. However, the hazardous situation could not cause significant harm.

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801  
802  
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804

**Outcome:** Continue to question 5.

**4.2. Adding new programming mode to a cardiac monitor**

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805 **Description:** The device is an implantable, automatically-activated monitoring system  
806 that records subcutaneous electrocardiograms. The manufacturer has made a software  
807 modification to add an alternative programming mode that allows the device to interact  
808 with the programmer. The mode introduces new technology that impacts the safety  
809 profile of the device as a result of the energy transfer that occurs during programming.  
810

#	Question	Yes/No	Rationale
4	<b>Does the change introduce a new hazardous situation or modify an existing hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?</b>	Yes	This feature introduces new hazardous situations based on the new programming mode that could cause significant harm as a result of energy transfer to the patient.

811  
812 **Outcome:** Submit the change in a new 510(k).  
813

814 **4.3. Imaging catheters – new optical module and new laser**  
815

816 **Description:** The device is an imaging catheter for coronary arteries that includes lasers  
817 and optical components. The manufacturer modifies the device software to integrate new  
818 optical modules and a new advanced laser method. The integration of the new  
819 components and function pose new risks related to interoperability, cybersecurity and  
820 performance of the device.  
821

#	Question	Yes/No	Rationale
4	<b>Does the change introduce a new hazardous situation or modify an existing hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?</b>	Yes	The change introduces new hazardous situations associated with interoperability. This change introduces a new hazardous situation as a result of the optical module not recognizing the new catheter and therefore not providing the correct laser settings, which could result in significant harm.

822  
823 **Outcome:** Submit the change in a new 510(k).  
824

825 **5. Flowchart Question 5 Examples**  
826

827 **5.1. Modification of a risk control**  
828

829 **Description:** The device is a robotically-assisted surgical system that utilizes position  
830 sensors. The system incorporates primary and secondary sensors to monitor the  
831 movement of actuators to prevent uncontrolled motion of the instrument in the event of a  
832 component failure. The system goes into a fault state and halts motion if the position  
833 information between the sensors does not match within a certain threshold. The threshold  
834 for each actuator is programmed in the software and there is a specification for how much  
835 overall movement is acceptable at the tip of the instrument before movement stops. The

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836 manufacturer makes a software change to the threshold settings for the position sensors;  
837 specifically, the software specification which defines the tip movement was widened.  
838 The change was made to minimize false assertion of the safety system, and the change in  
839 the specification for movement at the tip of the instrument was still within an appropriate  
840 safety tolerance for the device, as determined by analysis done by the manufacturer.  
841 However, the change modified an existing risk control (distance that can be travelled  
842 under fault conditions) that could significantly affect safety or effectiveness.  
843

#	Question	Yes/No	Rationale
5	<b>Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?</b>	Yes	The modified threshold values do not meet the specification for overall tip movement, which was required in the most recently cleared device to effectively mitigate the hazardous situation that could result in significant harm. Thus, the change necessitated modification of an existing risk control in the most recently cleared device. Thus, a new 510(k) is required.

844  
845 **Outcome:** Submit the change in a new 510(k).  
846

847 **5.2. Modification of threshold settings**  
848

849 **Description:** The device is a robotically-assisted surgical system that utilizes position  
850 sensors. The system incorporates primary and secondary sensors to monitor the  
851 movement of actuators to prevent uncontrolled motion of the instrument in the event of a  
852 component failure. The system goes into a fault state and halts motion if the position  
853 information between the sensors does not match within a certain threshold. The threshold  
854 for each actuator is programmed in the software and there is a specification for how much  
855 overall movement is acceptable at the tip of the instrument before movement stops. The  
856 manufacturer makes a software change to the threshold settings for the position sensors;  
857 specifically, the software was modified to better calculate overall movement. The change  
858 was made to minimize false assertion of the safety system, which required the surgeon to  
859 hit an override button to continue. This requirement can be a nuisance and distract from  
860 surgery. The modified software continued to meet the specification for movement at the  
861 tip of the instrument after a component failure.  
862

#	Question	Yes/No	Rationale
5	<b>Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?</b>	No	This change modifies sensor threshold parameters so that transient conditions that can be present during normal operation do not cause unnecessary activation of the risk control measure. The change makes the system more noise-tolerant without impacting true positive detection for the risk control measure. The overall movement criteria are met under all fault conditions.

863  
864 **Outcome:** Continue to Question 6.

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**5.3. Adding user interface alerts and controls**

**Description:** A manufacturer makes software modifications to replace existing modes of controls for handling samples having invalid characters in specimen IDs (specimen identification mis-association) received from Laboratory Information System or middleware vendors. Existing modes of control were adequate, but required operator interaction to evaluate whether a result record for a sample had an invalid Specimen ID. The new modes of control include a design improvement that will not generate results for a sample having an invalid specimen ID. Instead, the system software will: (1) generate a warning message to the operator that an invalid specimen ID was detected; (2) not generate or report results for a sample having an invalid specimen ID; and (3) create a system log entry.

#	Question	Yes/No	Rationale
5	<b>Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?</b>	Yes	This software change modifies the risk control which identifies invalid characters. If the invalid characters are not identified appropriately, then patient laboratory test results could be lost or replaced by incorrect results either of which could influence treatment decisions, which could cause significant harm.

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**Outcome:** Submit the change in a new 510(k).

**5.4. Print patient information on PACS report**

**Description:** A PACS provides the option to print images along with a copy of the diagnostic findings from the radiologist. There is data on each page allowing the user to match each page to the corresponding information (e.g., patient ID, Study Identifier). This data helps to address the known risk of pages being mixed-up after print-out. Based on customer preference, the manufacturer decided to enhance this existing risk control and have actual patient information and demographics printed on each page so it will be easier for the user to identify which pages belong together and, as a result, further decrease the risk of mixing-up printed pages.

#	Question	Yes/No	Rationale
5	<b>Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?</b>	No	The risk is already sufficiently mitigated with the original risk controls (that is, to have patient identification related information on each printed page). This software modification is a redundant risk control that was not made in response to a new, modified, or previously unknown hazardous situation or cause thereof.

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**Outcome:** Continue to Question 6.

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**5.5. Infusion pump alarm**

**Description:** A general purpose infusion pump has one alarm to alert the user when an occlusion has been detected. The software change is to provide 4 alarms related to occlusion: air in line, no upstream flow, occlusion downstream and occlusion upstream. These additional alarms provide specific information to help resolve the occlusion.

#	Question	Yes/No	Rationale
5	<b>Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?</b>	Yes	The change modifies the risk control, i.e., the alarm, which is already present for occlusion. This risk control is necessary to effectively mitigate the hazardous situation that could result in significant harm.

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**Outcome:** Submit the change in a new 510(k).

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**6. Flowchart Question 6 Examples**

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**6.1. Improve sample throughput 1**

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**Description:** A manufacturer makes a software performance enhancement to improve sample throughput time by 20%. Software modifications include changes to decrease assay cycle times by allowing for shorter sample reaction incubation times. Decreasing sample assay times could have an impact on run performance and/or assay performance in a manner that could have a negative impact on diagnosis or therapy delivered to patients.

#	Question	Yes/No	Rationale
6	<b>Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?</b>	Yes	The change is to increase the throughput performance specification but has a significant impact on the performance of the device, as there is a shorter reaction incubation time and therefore a potential significant impact on diagnostic utility and effectiveness.

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**Outcome:** Submit the change in a new 510(k).

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**6.2. Improve sample throughput 2**

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**Description:** A manufacturer is making a software modification to improve sample throughput by 5% by decreasing pre-analytic processing time. Software modifications include a change to decrease sample delivery time from the sample load area to the

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925 sample aspiration area. The change does not impact the sample analysis algorithm and  
926 has no impact on assay performance.  
927

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	No	The modifications do not impact assay performance as it relates to intended use. Improvement resulted from technical analysis of the sample delivery algorithm to optimize timing and remove unnecessary timing delays.

928  
929 **Outcome:** If the factors identified in Section VI are not relevant for this change,  
930 document the change to file.  
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#### 932 6.3. Analyzer remote monitoring feature improvement

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934 **Description:** A manufacturer makes a software modification to implement new  
935 functionality to an analyzer remote monitoring feature. The analyzer remote monitoring  
936 feature helps field service during remote troubleshooting of analyzer problems. The new  
937 functionality creates a system log of sample test result records that include calibration,  
938 quality control, and patient results. This log can be retrieved and reviewed remotely by  
939 field service. Software modification includes removing Personal Health Information data  
940 when writing from the system software database to the system log of sample test result  
941 records.  
942

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	No	The change is not required to support generation of test results and does not impact functionality or performance specifications that are directly associated with the intended use of the device.

943  
944 **Outcome:** If the factors identified in Section VI are not relevant for this change,  
945 document the change to file.  
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#### 947 6.4. Software change to modify summary window

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949 **Description:** A manufacturer makes a software modification to increase the number of  
950 images that can be viewed in a summary view for an ingestible telemetric gastrointestinal  
951 capsule imaging system. The new software allows for four images to be viewed  
952 simultaneously instead of two while a user reviews the images. The specifications for the  
953 image quality are not impacted by this change.

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	No	The change does not significantly impact functionality or performance specifications that are directly associated with the intended use of the device. Having more images in the window

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the device?	allows for the physician to review more images without increasing software loading time.
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**Outcome:** If the factors identified in Section VI are not relevant for this change, document the change to file.

**6.5. OEM module**

**Description:** A multi-parameter monitor device was originally cleared with version A of an original equipment manufacturer (OEM) module for blood oxygen saturation (SpO<sub>2</sub>). The OEM makes a change to version A of the SpO<sub>2</sub> sensor. This change does not impact the specifications for the SpO<sub>2</sub> module on the multi-parameter monitor but does necessitate a software change to include the new version number in a lookup table.

#	Question	Yes/No	Rationale
6	<b>Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?</b>	No	The clinical functionality is not affected. The change to the lookup table allows for this device to be recorded in event logs.

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**Outcome:** If the factors identified in Section VI are not relevant for this change, document the change to file.

**6.6. Home monitor**

**Description:** A home monitoring device that includes a Bluetooth module is changed to include the ability to transfer collected or acquired physiologic parameters (such as blood pressure, heart rate, and weight) to a mobile platform for tracking and trending only. The software is written in such a way as to isolate the transfer function from the rest of the device functionality so that it cannot impact the acquisition of the physiologic parameters.

#	Question	Yes/No	Rationale
6	<b>Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?</b>	No	The functionality added does not significantly affect clinical functionality or performance specifications and the implementation of the change could not impact any other function of the device.

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**Outcome:** If the factors identified in Section VI are not relevant for this change, document to file.

**6.7. Device reprocessor user interface change**

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985 **Description:** A device reprocessor display provides vital information on the temperature,  
986 the pressure, and the remaining cycle time. Software changes are made to increase the  
987 font size of these parameters on the display. The items are all in their same location and  
988 their appearance, aside from the larger size, is unchanged.  
989

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	No	Since the information was previously displayed, the change has no significant effect on the functionality or the performance of the device.

990  
991 **Outcome:** If the factors identified in Section VI are not relevant for this change,  
992 document the change to file.

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994 **6.8. Modify device algorithms**

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996 **Description:** A manufacturer makes a software modification to enhance an arrhythmia  
997 detection algorithm. The change impacts sensitivity and specificity, which are critical to  
998 the clinical performance of the device.  
999

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	Yes	The modification has direct impact on diagnostic performance of the device. Change directly supports performance specifications that could significantly impact the ability of the device to perform its intended use.

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1001 **Outcome:** Submit the change in a new 510(k).

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1003 **6.9. Modification to alarm duration**

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1005 **Description:** A manufacturer makes a software modification to allow users to silence a  
1006 low-risk alarm on a dialysis system. The change consists of a “snooze” button that  
1007 silences the alarm for a set amount of time before resounding.  
1008

#	Question	Yes/No	Rationale
6	Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?	No	The silencing of a non-critical alarm does not impact the clinical functionality. The criteria for the alarm are unchanged from the most recently cleared device.

1009  
1010 **Outcome:** If the factors identified in section VI are not relevant for this change,  
1011 document the change to file.