Matrix of needs for Traditional 510(k) Submission

For a Medical Device Release to Market

A DCG **"*iSubmission*"** Document

Sec	Description	Req	FDA Description	Needs and Responsibility
1	User Fee or 3rd Party Review	Y	1. Medical Device User Fee Cover Sheet (Form FDA 3601) The Medical Device User Fee Cover Sheet and receipt of the user fee payment, allow FDA to begin processing your submission; therefore, you should provide a Medical Device User Fee Cover Sheet with your 510(k) submission, unless it is a third-party review submission. Third-party review submissions are exempt from user fees. Although the following 510(k) submissions are also exempt from user fees, we recommend you include a Medical Device User Fee Cover Sheet, and use it to indicate the type of exemption that applies in the case of 510(k) submissions:. • intended solely for pediatric use (a change in the intended use from pediatric use to adult use requires the submission of a new 510(k) in accordance with 21 CFR 807.81 (a)(3); and an associated fee) • submitted by a state or Federal government entity (exempt from the FDA user fee unless the device is to be distributed commercially). The Medical Device User Fee Form may be obtained at www.fda.gov/oc/mdufmalcoversheet.html.See also Guidance for Industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions. (510(k)s) at	DCG and Client. Client must send payment to FDA.

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			www.fda.gov/cdrh/mdufma/guidance/1511.html.	
2	CDRH Cover Sheets	Y	CDRH Premarket Review Submission Cover Sheet The CDRH Pre-market Review Submission Cover Sheet is a voluntary form used to help provide basic administrative information for all types of pre market notification submissions. The Cover Sheet may be obtained at www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf.	DCG will produce w/client input on Standards
3	510(k) Cover Letter	Y	510(k) Cover Letter We recommend that you include a 510(k) Cover Letter with your submission. Guidance describes key information that may be useful to FDA in the initial processing and review of the 510(k) submission. In contrast with the CDRH Premarket Review Submission Cover Sheet from Section 2, the 510(k) Cover Letter described in Section 3 is intended to be more descriptive of a 510(k) submission.	DCG will produce. Will Need copies of Client Letterhead
4	Indications for Use Statement	Y	We recommend that you use this section to provide the indications for use statement, which is a document where you identify and describe the specific indications for use statement for the device(s) included in the 510(k) submission. Your indications for use statement should be exactly the same as the indications for use listed throughout the rest of your 510(k) submission, including the indications for use in the device labeling. We recommend that you use the Indications for Use Statement	Client to provide data.

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			Format at www.fda.gov/cdrh/devadvice/3l4312.h~l?11#link,",,6. We believe that in order for FDA to adequately review your submission you should identify whether the device is intended for prescription use and/or over-the-counter use.	
5	Summary	Y	510(k) Summary or S10(k) Statement In accordance with 21 CFR 807.87(h), each 510(k) submission must include either a 510(k) Summary (21 CFR 807.92) or 510(k) Statement (21 CFR 807.93). We recommend that you use Section 5 to provide the 510(k) Summary or 510(k) Statement.	DCG will produce from Client data.
6	Truthful and Accuracy Statement	Y	Truthful and Accuracy Statement In accordance with 21 CFR 807.87(k), all 510(k)s must include a statement certifying that all information submitted in the 10(k) is truthful and accurate and that no material fact has been omitted. The submitter should sign and date the statement. The 510(k) holder rather than a consultant or correspondent working for the holder should sign the Truthful and Accuracy Statement.	DCG will produce
7	Class III Summary and Certification	?	Class III Summary and Certification If your 510(k) is for a device type classified into class III for which we have not called for PMAs, it must contain a Class III Summary and Certification in accordance with 21 CFR 807.870) and 807.94. The Class III Summary and Certification provide a review of the risks and adverse events known and associated with the general category of devices	As required

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			into which the proposed device falls. We recommend that you use the Class III Summary and Certification format at www.fda.gov/cdrh/manual/stmnciii.htmi.	
8	Financial Certification or Disclosure Statement	?	Financial Certification or Disclosure Statement In accordance with 21 CFR 807.87(i), if you submit information from clinical studies, you must submit a financial certification *and/or* a disclosure statement for each clinical investigator who participated in your study. The following forms are available on our web site: • FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators, www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf • FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators, www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf See also 21 CFR Part 54 and the guidance entitled, Financial Disclosure by Clinical Investigators at www.fda.gov/oc/guidance/tinancialdis.html.	As required
9	Declarations of Conformity and Summary Reports	Y	Declarations of Conformity and Summary Reports If your 510(k) is an Abbreviated 510(k) submission, we recommend that you use this section to provide the information regarding any declarations of conformity to a standard or	DCG will produce.

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			a summary report recommended in any relevant device-specific guidance. As mentioned in the definitions section of this guidance, an Abbreviated 510(k) is a type of 510(k) in which you choose to declare conformance to a recognized standard for any part of the device design or testing or you choose to prepare a summary report to a guidance. More information about the FDA standards program, including a current list of FDA recognized standards may be obtained at www.fda.gov/cdrh/stdsprog.html.See also the guidances titled The New S10(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance at www.fda.gov/cdrh/ode/parad510.htmland Use of Standards in Substantial Equivalence Determinations at www.fda.gov/cdrh/ode/guidancel1131.html. If you choose to rely on a recognized standard or a guidance for any part of the device design or testing, you may include either a: • declaration of conformity to the standard" or summary report recommended in any relevant device-specific guidance; or • a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed. Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a	

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			declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(l)(B) of the act. Additional information regarding the use of declarations of conformity may be obtained at www.fda.gov/cdrh/devadvice/3145.html#link9.	
10	Executive Summary	Y	In this section of your 510(k), we recommend that you provide an executive summary of the 510(k), which should include a: • concise description of the device, including the indications for use and technology; • device comparison table; and • concise summary for any performance testing in the submission. The description, although concise, should be sufficient to provide an overall understanding of the device. The device comparison table should outline the differences and similarities between your device and the predicate. We recommend that you also provide a discussion of how this comparison supports substantial equivalence. The summary for each performance testing section (i.e., sections 18, 19, and 20) should be sufficient to provide a broad understanding of the type of testing performed, the methods used, and your conclusion from the results.	DCG will produce from Client data.
11	Device Description	Y	We recommend that you describe the performance specifications and include a brief description of the device design requirements in this section. We also	DCG will produce with input from Client. Require pictures, drawing (top level), etc.

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			recommend that you identify all models, as well as all accessories or components, included in the submission. If diagrams, dimensions, tolerances, and/or schematics are useful to fully describe and characterize the device, we recommend that you include them for each device, accessory or component included in the 510(k) submission. We also recommend that you provide a list of all patient contacting components and their respective materials.	
12	Substantial Equivalence Discussion	Y	In the substantial equivalence section, we recommend that you identify the predicate and identify its trade name, model number, 510(k) submitter/holder, and 510(k) number, if available. You may choose to identify, compare, and test against more than one predicate, if, for example, your device has two features or indications not previously combined in a single predicate. Our substantial equivalence determination is based on the 510(k) Substantial Equivalence Decision-Making Process Flowchart. We recommend that you provide a detailed comparison between your device and the predicate sufficient to demonstrate the substantial equivalence of the devices, as applicable, in terms of: • indications for use; • technology; and • performance specifications, including any testing. For additional background on making determinations of substantial equivalence we recommend that you refer to	DCG will produce.

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			Blue Book Memorandum K86-3 entitled Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86-3 at www.fda.gov/cdrh/k863.html.	
13	Proposed Labeling	Y	The 510(k) must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). If the device is an in vitro diagnostic device, the labeling should additionally satisfy the requirements of 21 CFR 809.10. Generally, the term "labeling" includes the device label, instructions for use, and any patient labeling. See also Labeling Requirements, at www.fda.gov/cdrh/devadvice/314312.html#link 10 and device specific guidance, where available, for more information about labeling your device.	Client input of labels on device and User Instructions. DCG will edit. Need copy of User Instructions in Microsoft Word format.
14	Sterilization	?	Sterilization and Shelf Life For devices sold as sterile, we recommend that you follow the guidance, Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA, at www.fda.gov/cdrh/ode/guidance/361.html. For devices that are reprocessed single use devices, please refer to Guidance for Industry and FDA Staff - Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (S10(k)s) for reprocessed Single-Use Medical Devices at www.fda.gov/cdrh/ode/guidance/1216.html. For a submission that identifies a shelf life for the device, your shelf life should be supported by appropriate bench tests and/or sterilization	Required if device is shipped sterile or can be sterilized.

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			(packaging) validation.	
15	Biocompatibility	?	If your device contains components that come into direct or indirect contact with patients, you should evaluate the biocompatibility of the patient-contacting materials. Please refer to the guidance documents titled Blue Book Memo, G95-1, Use of International Standard ISO-I0993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing at www.fda.gov/cdrh/g951.html.You should select biocompatibility tests for the duration and type of contact appropriate to your device design and submit the pass/fail criteria or in some cases, a summary of the results. If identical materials are used in a predicate with the same type and duration of patient contact, you may identify the predicate in lieu of performing biocompatibility testing and state that your device is comprised of identical materials and that are processed by identical manufacturing methods. This is most appropriate if you are the manufacturer of the predicate and you have complete documentation with respect to the manufacturing methods and materials employed.	Client to provide if required.
16	Software	?	This section should include the appropriate software documentation as described in the guidance titled Guidance for the Content of Pre market Submissions for Software Contained in Medical Devices at www.fda.gov/cdrh/ode/guidance/337.html.As discussed in the guidance, we recommend that you identify the "level of concern," (minor, moderate, or major) associated with your device and provide documentation consistent with that level.	Client to provide is device has software

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17	ECI and Safety Testing	?	If your device design includes an electronic component, we recommend that you evaluate its electromagnetic compatibility (EMC). EMC encompasses both emissions (interference with electronic products) and immunity (interference with device performance created by emissions from other electronic products). We recommend you test your device according to IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) or equivalent method to demonstrate the EMC characteristics of your device. If your device design results in patient contact with any electrically powered component, FDA recommends that you follow IEC 60601 1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995) or an equivalent method.	Client to supply
18	Performance Testing Bench	Y	If you submit bench test results to support substantial equivalence, we recommend you include the following information in this section. If the device is an in vitro diagnostic device, refer to Appendix B. You should describe the bench testing and provide the results that support the performance characteristics of your device. Generally, all submissions should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document.	Client to supply

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			• list the specific bench tests conducted • describe each test protocol • summarize the results • describe your analysis • discuss your conclusions The description of test protocols should identify the: • objective of the test • test articles used in the test • test methods and procedures (including any specific test conditions) • study endpoint, i.e., the specific parameter measured • pre-defined acceptance or pass/fail criteria. In the summary of your results and analysis, we recommend that you briefly present the data derived from testing in a clear and concise form, such as a table. We also recommend that your conclusions describe any comparison testing with the predicate in terms of substantial equivalence.	
19	Performance Testing – Animal	?	If you submit animal test results to support substantial equivalence, we recommend you include the following information in this section. I f you conducted animal testing, we recommend that you	Client to supply .

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			describe the tests and provide the results that support the performance characteristics of your device. Generally, all submissions that describe animal testing should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document. The branch or team responsible for the review of your device is also available to assist you with any questions about animal testing. • list the specific animal tests conducted • describe each test protocol • summarize the results • describe your analysis • discuss your conclusions The description of test protocols should identify the: • objective of the test • test articles used in the test • test methods and procedures (including any specific test conditions) • study endpoint, i.e., the specific parameter measured • pre-defined acceptance or pass/fail criteria. In the summary of your results and analysis, we recommend that you briefly present the data derived from testing in a clear and concise form, such as a table.	

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			We also recommend that your conclusions describe any comparison testing with the predicate device in terms of substantial equivalence.	
20	Performance Testing – Clinical	?	If you submit results from clinical studies to demonstrate substantial equivalence, we recommend you include the following information in this section. If the device is an in vitro diagnostic device, refer to Appendix B. FDA will always consider alternatives to clinical studies when the proposed alternatives are supported by an adequate scientific rationale. Our recommendations for clinical testing typically depend on many factors including device type, intended use, design, safety profile, and clinical experience. Generally, all submissions that describe clinical studies should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document. The branch or team responsible for the review of your device is also available to assist you with any questions about studies.	Client to supply .
21	Other - Usability if required.	?	CDRH considers human factors testing a valuable component of product development for medical devices. CDRH recommends that manufacturers consider human factors testing for medical devices as a part of a robust design control subsystem. However, in an effort to make CDRH's premarket submission expectations clear, CDRH has identified circumstances under which human factors validation testing should be submitted in a premarket submission. These devices noted below were selected because they have clear potential for serious harm resulting from use error. This identification was based on knowledge gleaned through Medical Device Reporting (MDRs) and recall information. Human factors data should be included in premarket submissions for these devices	

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			tasks, user interface, or use environments from those of the predicates. • Ablation generators (associated with ablation systems, e.g., LPB, OAD, OAE, OCM, OCL) • Anesthesia machines (e.g., BSZ) • Artificial pancreas systems (e.g., OZO, OZP, OZQ) • Auto injectors (when CDRH is lead Center; e.g., KZE, KZH, NSC) • Automated external defibrillators (e.g., MKJ, NSA) • Duodenoscopes (on the reprocessing; e.g., PDT) with elevator channels • Gastroenterology-urology endoscopic ultrasound systems (on the reprocessing; e.g., ODG) with elevator channels • Hemodialysis and peritoneal dialysis systems (e.g., FKP, FKT, FKX, KDT, KPF ODX, ONW) • Implanted infusion pumps (e.g., LKK, MDY) • Infusion pumps (e.g., FRN, LZH, MEA, MRZ) • Insulin delivery systems (e.g., LZG, OPP) • Negative-pressure wound therapy (e.g., OKO, OMP) intended for use in the home • Robotic catheter manipulation systems (e.g., DXX) • Robotic surgery devices (e.g., NAY) • Ventilators (e.g., CBK, NOU, ONZ) • Ventricular assist devices (e.g., DSQ, PCK) Note that FDA may recommend or require that human factors data be included in premarket submissions for additional device types though product specific guidance documents, special controls guidance or guideline documents, or special controls contained in medical devices classification regulations. Premarket reviewers may also determine that human factors data are needed in specific premarket submissions on a case-by-case basis	

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