O R A C L E

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NEWSLETTER FROM DELPHI CONSULTING GROUP (DCG)

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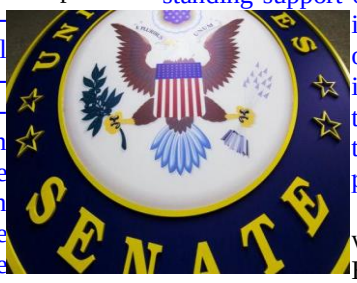
The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

Legislation to permanently repeal medical device tax introduced in Senate

More than seven months after the U.S. House of Representatives voted to permanently repeal the country's medical device tax, bipartisan legislation to accomplish the same goal has been introduced in the U.S. Senate. The bill was introduced Thursday, March 7, by Senators Pat Toomey (R-Pa.) and Amy Klobuchar (D-Minn.).



"The specter of the re-imposition of the punitive medical device tax threatens patients, American jobs, and medical innovation," Sen. Toomey said in a prepared statement. "It's time to end this uncertainty once and for all and finally repeal the medical device tax. I urge my colleagues to join this bipartisan effort."

The 2.3 percent tax returned at the beginning of 2018 after a two-year suspension, but was quickly suspended for another two years on Jan. 22. Without further action being taken, it would go back into effect in 2020.

In December 2018, a group of 12 U.S. governors wrote a letter to Senate Majority Leader Mitch McConnell and then-House Speaker Paul Ryan calling for the Senate to pass legislation repealing the tax.

Advocacy groups such as the Advanced Medical Technology Association (AdvaMed) Medical Imaging & Technology Alliance have also pushed for the tax to be permanently repealed.

"Today's Senate action is the first step in ensuring continued American leadership of this vital industry," Scott Whitaker, president and CEO of AdvaMed, said in a prepared statement. "We thank the bill's lead sponsors, Sens. Pat Toomey and Amy Klobuchar, for their long-standing support of improving patient lives and medtech innovation. The broad bipartisan backing of this bill reflects members' understanding of the negative impact on job creation, investment and patient care should this tax return, and the urgent need for repeal."

[Sic] Tin-horn politicians always want to call these things a "fee." How many ways does the government desire to tax medical device manufacturers? The thing is - any money paid to the government is a tax - period.

Reorganization of The Center for Devices and Radiological Health

The FDA's Center for Devices and Radiological Health (CDRH) is reorganizing to create an agile infrastructure that can adapt to future organizational, regulatory and scientific needs. This reorganization does not change the mission of CDRH or any MDUFA IV timelines.

Implementation of the reorganization will take a phased approach that will begin on March 18, 2019, and we expect to complete implementation by the end of September 2019. Updates on our progress will be posted on this webpage periodically.

Why is CDRH Reorganizing?

The CDRH reorganization will implement efficiencies that will allow us to more fully realize the FDA's and CDRH's public health mission and vision. Once fully implemented, reorganization will integrate CDRH's premarket and postmarket program functions along product lines allowing our experts to leverage their knowledge to optimize decision-making across the product life cycle.

Historically, CDRH has been organized according to the stage of the product's life cycle—premarket review, postmarket surveillance, and compliance—rather than holistically by the type of product being regulated. Although that structure allows employees to become specialized by function, it does not always promote the type of communication and collaboration that is proving essential to the continuously evolving innovation of medical devices.

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Since June 2018, we have been piloting a more integrated approach to device safety throughout the Total Product Life Cycle (TPLC). Although CDRH has applied a TPLC approach to devices for many years, the reorganization will enhance communication among CDRH staff and enable more efficient activities across the life cycle from premarket review to postmarket surveillance.

What is the Benefit of CDRH Reorganization?

The goal of the CDRH reorganization is to improve organizational efficiencies to better meet public health needs. Once fully implemented, CDRH's premarket and postmarket program functions will be integrated along product lines. This type of structure consolidates and integrates many of the current aspects of product review, quality, surveillance and enforcement into a new, team-based approach. Rather than assessing a device only at one point in time—for instance, to evaluate whether a device meets the standard for approval, or to evaluate postmarket data involving a device safety signal—reviewers, compliance officers and other experts would work in teams responsible for device oversight throughout the product's development and commercialization.

What is the Timeline for Implementation of the CDRH Reorganization?

Implementation of the CDRH reorganization will take a phased approach that will begin on March 18, 2019. Full implementation of the reorganization will be completed by September 30, 2019.

What Are the Changes to CDRH's Organizational Structure?

During implementation, each office within the current Center structure will undergo some change to better support and advance CDRH's public health mission and vision.

Medical Device Development Tools (MDDT)

The FDA's Medical Device Development Tools (MDDT) program is a way for the FDA to qualify tools that medical device sponsors can use in the development and evaluation of medical devices.

Qualification means that the FDA has evaluated the tool and concurs with available supporting evidence that the tool produces scientifically-plausible measurements and works as intended within the specified context of use.

The context of use depends on:

- the tool or product area in which the tool is proposed for qualification
- the specific output or measure from the MDDT
- the role of the MDDT (for example, for clinical uses, including the study population or disease characteristics, as well as specific use-diagnosis, patient selection, and study endpoints), and
- the phases of medical device development during which the MDDT or tool measurements can be used (for example, design evaluation or early clinical study).

More information about the context of use is in the final guidance on Medical Device Development Tools. The MDDT program promotes innovation in medical device development and regulatory science to help bridge the gap between research of medical devices and the delivery of devices to patients.

MDDT Categories

The FDA has defined three categories of MDDT:

- **Clinical outcome assessment:** measures of how a patient feels or functions. These could be patient-reported or clinician-reported rating scales like the NIH stroke scale, measures based on clinical decision-making, observer-reported outcomes such as from a parent or caregiver, or performance outcome measures, such as measures of gait speed or memory recall.
- Examples of tools that might be eligible for qualification include: patient reported outcome rating scales, such as those used to measure pain, improved mobility, symptom relief, function, or health status and heart failure-related hospitalization.
- **Biomarker test:** a lab test or instrument used to detect or measure an indicator of biologic processes or pharmacologic responses to a treatment (biomarker).
- Examples of tools that might be eligible for qualification include: tests used as an aid in diagnosis, for patient selection, or as clinical study endpoints, such as instruments or methods for measuring blood pressure; or instruments or methods for measuring certain concentrations of serum proteins, such as an assay to detect the level of a specific hormone in a patient in order to determine enrollment eligibility for study population in a clinical trial.
- **Nonclinical assessment model:** a nonclinical test method or model (e.g. in vitro "bench," animal or computational model) that measures or predicts device function or performance in a living organism.
- Examples of tools that might be eligible for qualification include: models used to measure a parameter of interest or to substitute for another generally accepted test or measurement, such as computer modeling to assess conditions typically evaluated through human, animal or bench testing to evaluate a device instead of collecting data from human subjects; use of tissue and other material phantoms to evaluate imaging devices; or In vitro models to replace animal testing.

More information about the categories of MDDT is in the final guidance.

How to Participate in the MDDT Program

The goal of the voluntary MDDT program is to assess and refine the qualification process for tools used to develop and evaluate medical devices. The program aims to provide MDDT developers and medical device manufacturers with a mechanism for discussing early concepts about a tool, fostering collaboration on tool development, and potentially increasing adoption and use of the qualified tools.There are no fees associated with submitting a tool for qualification.

Any tool developer, medical device manufacturer, or others such as research organizations and academia can voluntarily submit a proposal as an eCopy. The eCopy should be in the form of a CD, flash drive, etc., and

should be sent to the Document Mail Center at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The eCopy should meet the technical standards outlined in Attachment 1 of the FDA guidance "eCopy Program for Medical Device Submissions."

The proposal should be submitted as an "informational meeting" Q-submission based on the FDA guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff." The cover sheet contents should follow the enclosure: Proposal Cover Sheet. If you have any questions, please contact us at MDDT@fda.hhs.gov.

Qualification Process

The voluntary qualification process consists of several phases described below.

Proposal phase

The goal of the proposal phase is to determine if the MDDT is suitable for qualification through the MDDT program. Those interested in seeking qualification should submit a complete proposal package, including a description of the MDDT, and a justification for how the MDDT will help address a public health need.

Incubator phase (optional)

In certain instances CDRH may accept MDDTs with a high potential public health impact that are not fully developed. The goal of the incubator phase is for CDRH to work with submitters to foster the development of tools that have potential to significantly improve public health. CDRH will determine whether this phase is necessary.

Pre-Qualification phase (optional)

During the pre-qualification phase, CDRH can provide feedback to submitters on their plan to collect evidence to support qualification of the tool. CDRH will determine whether this phase is necessary.

Qualification phase

The goal of the qualification phase is to determine whether, for a specific context of use, the tool is qualified based on the evidence and justifications provided.

More details about the phases are available in the final guidance.

Qualification Decision

The FDA considers the following when determining whether to qualify a proposed MDDT:

- **MDDT description.** Is the MDDT adequately described?
- **Context of use.** Is the proposed context of use adequately and appropriately defined?
- **Public health impact.** Would the scope and use of the tool have a broad public health impact?
- **Strength of evidence.** Does the available scientific evidence demonstrate that the MDDT reliably and accurately measures what is intended, is scientifically plausible, and is reasonably likely to predict the outcome of interest?
- **Assessment of advantages and disadvantages.** Within the specified context of use and given the available strength of evidence, do the advantages outweigh potential disadvantages of making decisions based on measurements obtained using the MDDT? Of particular importance are regulatory, public health, and/or clinical impact.

Qualified Tools

The FDA is excited to announce that we have qualified the first tool under the MDDT program.

The FDA will publicly list MDDTs in the table below once they are qualified, along with a summary of evidence and basis of qualification for the tool. This information includes a brief description of the tool, the qualified context of use, a general summary of evidence to support qualification, a brief assessment of the advantages and disadvantages, and information on how to contact the tool developer about accessing the tool.

Name of Tool	Summary of Evidence and Basis for Qualification (SEBQ)	Product Area(s)
OSIRIX CDE Software Module	Qualification Summary	Neuro
Minnesota Living with Heart Failure Questionnaire (MLHFQ)	MLHFQ Qualification Summary	Cardio
Kansas City Cardiomyopathy Questionnaire (KCCQ)	KCCQ Qualification Summary	Cardio

The FDA will not place limitations or requirements on MDDT licensing or fees, or the degree of access to intellectual property associated with an MDDT that a tool developer may give to a device sponsor. Prior to participating in the program, the tool submitter can discuss with the FDA during the proposal phase the level of information they deem appropriate for public disclosure.

The FDA only intends to qualify tools where the information contained in the summary of evaluation and basis for qualification can be made public.

More information about the qualification process is in the MDDT Program Federal Register Notice.

Additional Resources

- Summary of Evidence and Basis of Qualification (SEBQ) Template (PDF - 353KB)
  This template includes the types of information the FDA will post once an MDDT is qualified.
- Webinar - CDRH Final Guidance: Qualification of Medical Device Development Tools - August 24, 2017
  The page contains links to meeting materials for the CDRH Final Guidance: Qualification of Medical Device Development Tools Webinar held on August 24, 2017.