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LIFE SCIENCES UPDATE

FDA Proposes to Clarify and Clearly Define Rules Regarding Medical Device Approval Procedures

On August 4, the Food and Drug Administration (FDA) released its lengthy 510(k) Working Group Preliminary Report and Recommendations (“Report”) in an effort to clarify and more clearly define the existing and commonly used review rules for medical devices. There has been widespread criticism of the existing medical device regulations, as they are perceived to be ambiguous and inconsistently applied. As such, the FDA released its Report that focuses on three key objectives: fostering device innovation, creating a more predictable regulatory environment and enhancing device safety.

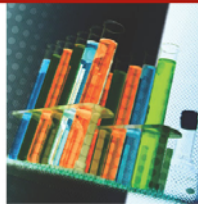
MEDICAL DEVICE APPROVAL PROCESS AND CLASSIFICATIONS

The FDA regulates the sale and marketing of medical devices. A medical device is defined within the Food Drug & Cosmetic Act (FDCA) as “...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar...article...intended for use in the diagnosis of disease or other conditions, or in the cure...treatment...or prevention of disease...which does not achieve...its primary intended purposes through chemical action within or on the body...”

The Center for Devices and Radiological Health (CDRH), within the FDA, is responsible for assuring that marketed medical devices provide a reasonable assurance of safety and effectiveness for their intended use prior to marketing. For purposes of approval and regulation, medical devices fall into one of three classes. This classification is based upon the risk presented by the medical device to the patient and the necessary level of regulatory control required to legally market the device to the public. As the class level increases, so too does the risk to the patient and the required level of FDA regulatory control.

Class I devices are fairly simple in design, and easy and safe to use. Examples of Class I devices include tongue depressors, enema kits, elastic bandages and hand-held surgical instruments.

Class II medical devices are subject to General Controls and Special Controls compliance. Special Controls include labeling requirements, mandatory performance standards, post-market surveillance and medical device specific guidance. These devices are generally cleared for marketing under section 510(k) of the FDCA, which allows device makers to market new medical devices that are substantially equivalent to “predicate devices” that were lawfully marketed prior to the 1976 amendment. This permits new device manufacturers to market their own versions of predicate devices without the burden of conducting new clinical studies. Examples of Class II devices include physiologic monitors, powered wheel chairs, surgical drapes and pumps.



Class III medical devices are those that support and sustain human life. General Controls and Special Controls are not sufficient to assure safety and effectiveness of Class III devices and thus, additional regulation (such as Pre-Market Approval (PMA)) is needed. Examples of Class III medical devices include pacemakers, replacement heart valves, silicone gel-filled breast implants and implanted cerebella stimulators.

KEY OBJECTIVES FOR THE MEDICAL DEVICE APPROVAL PROCESS

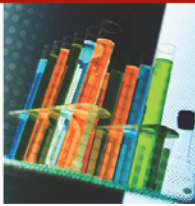
Fostering Device Innovation

In order to foster device innovation, the Report recommends major improvements to the regulatory pathway for lower-risk novel devices that cannot be cleared through 510(k), as they do not have a predicate device, but that do not warrant the more rigorous premarket approval review applied to higher-risk devices. The Report calls for major reforms in the implementation of the existing Evaluation of Automatic Class III Designation, also known as the “*de novo* classification process.” The recommendations include streamlining the process and clarifying the FDA’s expectations for submissions that undergo this type of review. Reforms to the *de novo* classification process are intended to provide a practical, risk-based option that allows appropriate levels of review and regulatory control.

Creating a More Predictable Regulatory Environment

To create a more predictable regulatory environment, the Report proposes the administrative creation of a subset of Class II devices, called Class IIb, for which clinical or manufacturing data typically would be necessary to support a substantial equivalence determination. This guidance document would help clarify the information that should be included in 510(k) submissions so that the industry can plan accordingly. In addition, this would also assist the CDRH’s review staff obtain the type and level of evidence necessary to make well-supported decisions while decreasing time-consuming follow-up requests for information.

Creating a more predictable regulatory environment also involves correcting ambiguities and providing clarity regarding the definition of pivotal regulatory terms. Although the 510(k) approval process of a new medical device is dependent on the manufacturer proving that the new device is *substantially equivalent* to a *predicate device*, there exists a lack of clarity with respect to the definition of “substantially equivalent.” Ambiguity also exists with respect to determining what constitutes a new “intended use” of a medical device versus a prior approved use, and when different technological characteristics raise different questions of safety and effectiveness. For example, if a modern device is intended for treatment of the same condition as a predicate device but operates with vastly different technology, does it raise new questions of safety and effectiveness? This vagueness has resulted in confusion in the industry and inconsistent decision-making by the CDRH. As such, it is necessary for the FDA to more clearly define these crucial terms for the benefit of both industry and FDA reviewers.



Enhancing Device Safety

To enhance device safety, the Report recommends revising regulations to explicitly require 510(k) submitters to provide a summary of all scientific information known, or that reasonably should be known, by them regarding the safety and effectiveness of the device under review. This is not currently required for 510(k) submissions and, as a result, relevant information may not be included in an initial submission. This summary is expected to help FDA review staff to more efficiently make decisions, and to potentially avoid extensive follow-up inquiries and questions.

The Report also proposes the development of guidance to clarify when a device should not be used as a predicate, such as when it was removed from the market because of safety concerns. Also included in the Report is a recommendation for clarification of the circumstances under which the CDRH would exercise its authority to rescind a 510(k) clearance in order to remove an unsafe device from the market and to preclude its use as a predicate device.

In its Report, the FDA also urges the enhancement of public and internal databases to include meaningful, up-to-date information that supports good decision-making and promotes the safe use of devices. The FDA believes this could be accomplished by providing easier user access and improving the current 510(k) database to include summaries of FDA review decisions, current labeling and schematics and photographs.

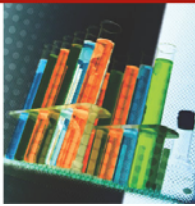
CONCERNS RAISED BY THE REPORT'S RECOMMENDATIONS

Some fear that the Report's recommendations, which impose more stringent rules on the medical device regulatory and approval process, may result in higher product development costs, which will in turn be passed on to consumers.

Many in the industry are concerned with portions of the Report that call for the updating of public databases with summaries of FDA review decisions, current labeling and device photos and schematics. The industry fears that the information recommended to be disclosed in the public database does, or may in the future, include sensitive, proprietary and confidential device and company information, which may be improperly appropriated by domestic and foreign competitors.

WELCOMED CHANGES

A common frustration for the industry arises from the variation in the expertise, experience and training of reviewers and managers which may contribute to inconsistency or uncertainty in 510(k) decision-making. The FDA's Report addresses this issue by advocating taking steps to enhance recruitment, retention, training and professional development for all of its staff (including reviewers); and the creation of a Center Science Council. The purpose of this council, comprised of experienced reviewers and managers, is to provide oversight and to facilitate knowledge-sharing across FDA branches, divisions and offices with the ultimate goal of improving the consistency of the CDRH's decisions.



To address criticisms that the FDA lacks an adequate mechanism to properly assess the quality, consistency and effectiveness of the 510(k) program, the Report recommends the enhancement of the FDA's systems and program metrics to support continuous quality assurance. As this area of enhancement is not clearly defined, members of the industry are invited to make recommendations.

IMPACT OF THE FDA RECOMMENDATION REPORT

If and when implemented, the changes to the medical device approval regulations and processes recommended by the Report will be widely and immediately felt by the more than \$200 billion U.S. medical device industry. It is expected that the proposed rules and recommendations will streamline the medical device approval process, resulting in a uniform system that is predictable and cost-effective to the industry and the public. As such, the medical device community can plan accordingly by setting proper budgets and approval strategies to assess the likelihood of success of a medical device 510(k) application. The changing medical device environment may require device makers to make substantial changes to their devices, including their manufacturing, labeling and marketing practices.

Although the Report potentially paves the way for new and efficient medical device approval procedures, it is preliminary and many of the recommendations and proposals are general concepts, not yet fully developed. As such, the FDA invites members of the industry to offer proposals and recommendations, including those regarding the feasibility of implementation and potential alternatives. The FDA plans to hold hearings on these matters in the near future.

FOR MORE INFORMATION

Our lawyers are available to address the questions, comments and concerns of those in the medical device community who may be affected by the changing environment. For more information, please contact:

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