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Client Alert

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CDRH Plan of Action to Improve the 510(k) Process

In August 2010, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) released for public comment the preliminary reports from the 510(k) Working Group and Task Force on the Utilization of Science in Regulatory Decision Making. These committees were charged with evaluating the 510(k) program and exploring actions CDRH could take to enhance the effectiveness and predictability of the 510(k) clearance process and the incorporation of new scientific information by CDRH into its decision making. Following the release of these reports, the FDA received a range of perspectives during the public comment period.

On January 19, 2011, the CDRH published its 510(k) and Science Report Recommendations and the actions the agency intends to implement in 2011. For some of the 25 action items that the CDRH intends to implement during 2011, there will be additional opportunities for the public to provide comment. Recommendations that are regulatory actions, such as draft guidance and proposed regulations, will have their own individual comment periods. The CDRH may also issue device-specific guidance when appropriate. The CDRH also noted it will give the Institute of Medicine (IOM) an opportunity to provide feedback on seven recommendations about which significant concerns were raised in comments submitted to the public docket.

This Bulletin summarizes these 25 action items.

Guidance Documents

There are eight action items that will be addressed by draft guidance documents. The most significant guidance documents and their expected completion dates are as follows:

- Guidance on 510(k) modifications to clarify which changes do or do not require the submission of a new 510(k) or which may be eligible for a Special 510(k).
- Guidance to improve the quality and performance of clinical trials (expected July 31, 2011).
- Guidance to streamline the *de novo* classification process (expected September 30, 2011). The guidance document will clarify the evidentiary expectations for *de novo* requests. According to the CDRH, the Guidance will allow sponsors of low-to-moderate risk devices without a

predicate to decide earlier on whether the *de novo* process is more appropriate than the 510(k) review process, thus saving the sponsor and the CDRH time and money. Note the *de novo* classification process is an alternative regulatory pathway, intended to apply to lower-risk devices that are classified into Class III through the 510(k) process. A 510(k) submitter who receives a Not Substantially Equivalent (NSE) determination may request a *de novo* classification of the device into Class I or II. Our firm previously published an AGG Client Alert on the *de novo* review process. To view this Alert, please click here.[1]

- Guidance on the 510(k) paradigm (expected September 30, 2011). The CDRH hopes to provide greater clarity regarding the following:
  1. when clinical data should be submitted to support a 510(k);
  2. the submission of photographs or schematics for internal FDA use only;
  3. the appropriate use of multiple predicates;
  4. the criteria for identifying "different questions of safety and effectiveness;"
  5. resolving discrepancies between the 510(k) flowchart and the Federal Food, Drug and Cosmetic Act;
  6. the characteristics that should be included in the concept of "intended use;" and
  7. the development of 510(k) summaries to assure they are accurate and include all required information.
- Guidance to clarify the process for appealing CDRH decisions, including decisions to rescind a 510(k) clearance (expected October 31, 2011).
- Guidance to clarify the appropriate use of consensus standards (expected October 31, 2011).
- Guidance to supplement available guidance on pre-Investigative Device Exemption (IDE) meetings and enhance the quality of pre-submission interactions between industry and CDRH staff (expected November 30, 2011).
- Guidance on product code to more consistently develop and assign unique product codes (expected December 31, 2011).

There will be an opportunity for comment after the guidance documents are issued.

Internal and Administrative Matters

Six action items address internal staff requirements and training, as well as the development of standard operating procedures (SOP) for staff engagement with external experts. Notably, the FDA is considering establishing a Center Science Council by March 31, 2011, which will, among other things:

1. oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information;
2. promote improvement of metrics to assess the quality, consistency and effectiveness of the 510(k) program;
3. periodically audit 510(k) review decisions; and
4. establish an internal team of clinical trial experts to provide support and advice on clinical trial design for CDRH staff and prospective IDE applicants.

1 http://www.agg.com/media/interior/publications/Kitchens_Minsk_Nguyen-510(k)ProgramPreliminaryReports.pdf

The FDA will post the Council Charter and initial results of 510(k) audits on its website.

With respect to other internal and administrative matters action items, the CDRH also plans to assess its staff needs (expected July 15, 2011), enhance training of CDRH staff (expected August 31, 2011), leverage external experts (expected September 15, 2011), and continue efforts for integration and knowledge management across centers (expected September 30, 2011).

Programmatic and Regulatory Matters

Of the 25 specific items under the plan of action, the initiation of a pilot program by March 31, 2011, for use of an assurance case framework for the 510(k) program is likely to have the most immediate impact on medical device manufacturers. The "assurance case framework" is a formal method for development of the data and evidence to support the validity of a claim. The assurance case will require the manufacturer to substantiate each claim and not simply compare the device to claims made by the predicate device.

Further, the CDRH is also considering establishing a "Notice to Industry Letters" as a standard practice to clarify to manufacturers when the CDRH has changed its regulatory expectations on the basis of new scientific information. Moreover, the CDRH plans to issue a proposed regulation to implement a unique device identification (UDI) system. In addition, the CDRH plans to issue a regulation by December 31, 2011, to track transfers of 510(k) ownership. This is important, because the CDRH has never tracked ownership of 510(k) clearances.

Other regulatory action items include:

- The CDRH will provide additional information about regulated products by making device photographs available in a public database without disclosing proprietary information. The FDA will also hold a public meeting regarding additional information about regulated products (expected April 7-8, 2011).
- The CDRH will improve the IDE process to better characterize the root causes of existing challenges and trends in IDE decision making. The CDRH plans on completing a program assessment by June 30, 2011.
- The CDRH will improve collection and analysis of postmarket information. Specifically, the CDRH plans to determine system requirements and select the platform for a new adverse event database (expected June 30, 2011).
- The CDRH will improve medical device labeling by establishing an online labeling repository and clarifying the statutory listing requirements for the submission of labeling. The CDRH will hold a public meeting to discuss the online labeling repository and statutory listing requirements in April 2011. The CDRH plans to issue proposed regulations on the statutory listing requirements by the end of the year.
- The CDRH will conduct additional analysis to determine the basis for the apparent association between citing more than five predicates and a greater mean rate of adverse event reports. The analysis will be completed and made available to the public by October 31, 2011.
- The CDRH will develop a process to clarify third-party review (September 30, 2011).

Issues to be Referred to IOM

The plan of action contains seven issues to be referred to the IOM for additional analysis. The IOM will review the following by issuing an IOM Report by the summer of 2011:

- Consider defining the scope and grounds for exercising CDRH authority to fully or partially rescind a 510(k) clearance;
- Seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices;
- Develop guidance defining "class IIb" device for which clinical information, manufacturing information or potentially additional postmarket evaluation would be necessary to support a substantial equivalency decision;
- Clarify when a device should no longer be available for use as a predicate;
- Consolidate the concepts of "indication for use" and "intended use" into the single term, "intended use;"
- Consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for the CDRH to access upon request; and
- Explore the possibility of pursing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of the device.

The view the full plan of action, please click here.[2]

The CDRH plans to post updates on the status of planned actions on its website.

2 http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm