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FDA to Begin Revamping the 510(k) Medical Device Review Program

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In September 2009, the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) established both the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making to address a myriad of concerns over whether the operation of the 510(k) program was in fact predictable for medical device manufacturers, facilitated medical device innovation, and protected public health and safety. In August 2010, the working group and task force issued preliminary reports recommending a total of 55 changes to the 510(k) program. The FDA invited public and industry comment on the reports.

On January 19, 2011, the FDA announced that during the comment period it received feedback on each of the 55 recommendations; some of the recommendations received broad support, some received support with a suggested modification or caveat, and on some there were significant reservations. As a result, the FDA further announced that it planned to begin implementing 25 of the recommendations on which there was support, or support with some modification, focusing initially on recommendations that, per the FDA, will have the greatest impact on either fostering medical device innovation, enhancing regulatory predictability, or improving patient safety. Several of the remaining recommendations are being referred to the Institute of Medicine for feedback. Some will be implemented at a later point, after further consideration or modification. Click here to read the full FDA report.

Significantly, the FDA announcement indicated that the more controversial of the August 2010 recommendations—such as the creation of new device classifications for which additional evaluation is necessary for 510(k) clearance, the creation of grounds for full or partial rescission of 510(k) clearance, and the creation of authority for the FDA to consider off-label usage in certain circumstances when determining “intended use” of a device under 510(k) review—were put off, at least until the Institute of Medicine review, which is expected in the summer of 2011.

The initial changes being implemented within the next year are generally designed to increase both the efficiency and transparency of the review process. These include enhanced training and professional development for CDRH staff, enhanced internal processes for knowledge sharing amongst CDRH staff, the development of standardized procedures and/or guidance for both staff and industry, improvement of data sources, clarifying the circumstances and processes for clinical data requests, and increased use of outside reviewers/experts.

But the implementation plan the FDA published on January 19, 2011, illustrates the timetable is staggered. The first recommendations to be implemented include instituting a pilot program using an “assurance case” framework for 510(k) submission (by March 31, 2011); developing and posting a charter for a Center Science Council to oversee development of business processes, operating procedures, and review mechanisms (by March 31, 2011); and holding a public meeting on development of an online labeling repository and a public database for photographs (April 7–8, 2011).

Key dates include the completion of draft guidance for 510(k) modifications (by June 15, 2011), completion of draft guidance for clinical trials (by July 31, 2011), and selecting a platform for a new adverse event database (by June 30, 2011). Click here for more information on the implementation schedule.

The FDA is soliciting questions, as well as feedback, on the published Plan of Action for the Implementation of 510(k) and Science Recommendations. Click here to submit questions or feedback to the FDA's web site.

Mintz Levin attorneys will be monitoring the continuing evolution of the 510(k) process, and remain available to assist with the submission of comments or to answer any other questions.

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