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HINE**

September 2011

PRODUCT LIABILITY UPDATE**FDA Issues Draft Guidance on Medical Device Clinical Investigations Intended to Support Premarket Submissions**

The Food and Drug Administration (FDA) recently issued its Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff: Design Considerations for Pivotal Clinical Investigations for Medical Devices (Draft Guidance) for review and comment.¹ The Draft Guidance lays out the principles that researchers and manufacturers should follow in designing clinical studies in support of premarket approval applications (PMAs) for medical devices. Draft Guidance at 4, 5. While it provides no bright line rules regarding the types of clinical study designs medical device manufacturers should use, it provides insight into FDA's current views regarding clinical investigation, which favor the use of randomized clinical studies. The guidance primarily will impact devices being brought to market through PMA submissions.

The Draft Guidance is part of FDA's efforts to reevaluate and revamp the current system for pre-market medical device clearance and approval. FDA's efforts to evaluate the premarket submission process began more than two years ago when it created the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making and charged the groups with evaluating and recommending improvements to both the 510(k) program and the PMA process. Following notice and comment on the groups' preliminary reports (which included 55 recommendations),² FDA issued 510(k) and Science Report Recommendations, identifying more than 20 recommended steps for FDA to improve the 510(k) and PMA approval programs including, but not limited to:

- Improving the quality of the design and performance of clinical trials used to support PMA applications by developing guidance on the design of such trials
- Continuing efforts to develop better data sources, methods, and tools for collecting and analyzing meaningful postmarket information
- Providing greater clarity regarding the circumstances in which clinical data in support of a 510(k) will be requested, including the type and level of clinical data that are adequate to support clearance
- Developing training regarding the delineation between "class IIa" and "class IIb" devices³

FDA subsequently released its Plan of Action for Implementation of 510(k) and Science Recommendations, which contained 25 actions that it intended to take by the end of 2011, such as issuing draft guidance related to modifications warranting new 510(k) submissions, evaluating the *de novo* process (whereby devices found not substantially equivalent to existing predicates may be



reclassified as Class I or II devices if they are low risk), and clarifying the process for appealing Center for Devices and Radiological Health (CDRH) decisions to rescind a 510(k) clearance.⁴

FDA also charged the Institute of Medicine (IOM) with reviewing the 510(k) clearance process to determine whether the current process protects patients optimally while promoting innovation in support of public health and, if it does not, to identify the changes that could more optimally achieve the goals of the 510(k) clearance process. On July 29, 2011, the IOM released its report which, instead of providing action items to strengthen the current 510(k) process, recommended that the 510(k) process be abandoned in favor of “an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle” – a recommendation that would require extensive development by FDA and the enactment of legislation by Congress.⁵ While FDA has rejected the IOM’s recommendations, it is poised to continue its reform of the 510(k) and PMA processes in ways that likely will substantially alter the landscape for future medical device clearance and approval.

The Draft Guidance related to design considerations is one of the first steps FDA has taken in the process of evaluating the premarket submission process.⁶ FDA plans to issue draft guidance by the end of September related to streamlining the *de novo* classification process and will issue draft guidance by the end of October aimed at clarifying the appropriate use of consensus standards and clarifying the process for appealing CDRH decisions, including decisions to rescind a 510(k). While it still is unclear how far FDA will go in revising the current premarket submission process, it is clear that change is coming.

FDA is taking public comments on this Draft Guidance through November 14, 2011. By offering public comment, medical device companies can impact the ultimate regulatory framework applicable to clinical investigation. Therefore, medical device companies should consider commenting on the Draft Guidance by informing FDA of their related experiences, concerns, and suggestions. Thompson Hine’s lawyers are available to advise and assist those in the medical device community who may be affected by the Draft Guidance or the changing regulatory environment.

FOR MORE INFORMATION

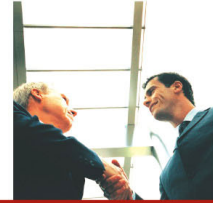
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¹ A copy of the [Draft Guidance](#) can be obtained on FDA's website.

² A copy of the [510\(k\) Working Group Preliminary Report and Recommendations](#) can be obtained on FDA's website, as can a copy of the [Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations](#).

³ A copy of the [Report and Recommendations](#) can be obtained on FDA's website.

⁴ A copy of the [Plan of Action for Implementation of 510\(k\) and Science Recommendations](#) can be obtained on FDA's website.

⁵ A copy of the IOM's [Consensus Report](#) can be obtained on IOM's website.

⁶ On the same day, FDA issued Draft Guidance for Industry and Food and Drug Administration Staff – Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review. See Thompson Hine's [Product Liability Update](#) related to that draft guidance for more information.