



September 21, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

Docket No. FDA-2010-N-0348

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) 510(k) Working Groups' Preliminary Report and Recommendations on the Agency's device clearance process. AACC supports the FDA's efforts to clarify and streamline the current 510(k) review mechanism. We believe that clearer, more predictable guidance, in conjunction with needed regulatory reforms, will better serve medical device manufacturers, the health care community, and the public alike.

De Novo Process

The 510(k) Working Group found that "Although there exists an alternative regulatory pathway for devices that lack a clear predicate but whose risks do not warrant class III controls...this pathway, as currently implemented, is inefficient and has not been utilized optimally across the Center." On the basis of this finding, the Group recommends that the FDA "reform its implementation of the de novo classification process to provide a practical, risk-based option that affords an appropriate level of review and regulatory control for eligible devices."

AACC strongly supports the Working Group recommendation. Congress authorized the de novo process to allow the agency to reclassify low risk devices that would automatically be designated as Class III devices, solely because there is no predicate device, as Class I or II. This means that manufacturers, in certain instances, are able to seek clearance through the less burdensome 510(k) process, rather than the more costly and onerous pre-market approval (PMA).

Unfortunately, confusion over evidentiary requirements, along with the length of time associated with Agency review, has discouraged many IVD manufacturers from pursuing this route. In each of the past few years, the Office of Vitro Diagnostic (OIVD) has received only one IVD de novo submission. Since 2005, the length of time for each review has averaged 311 days—50 days longer than the baseline year. We are confident, however, that the number of de novo applications would increase substantially, and the review time decrease, if the process were more clearly defined and predictable.

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The use of the de novo process is particularly important for devices, such as tests for Therapeutic Drug Monitoring (TDM), where consumer demand is often limited, but the potential for improved patient care is significant. Shifting the review of a low volume, low risk test from a PMA to a 510(k) review may make development of a previously unprofitable test, now cost-effective. This change benefits the manufacturer, which now has an incentive to develop and market the test, as well as the patient, who now has access to a valuable test for managing their drug therapy.

Use of Predicate Devices

The Working Group also identified the quality of some predicate devices to be an issue of concern. The panel recommended that “CDRH should explore the development of guidance and regulation to provide greater assurance that any comparison of a new device to a predicate is valid and well-reasoned.” AACC agrees with this recommendation. Not all predicate devices are the same. Many are of high quality, but some may be substandard, and possibly not in use anymore. The FDA should ensure that a predicate meets the agency’s safety and effectiveness criteria, as well as serves as a valid comparison.

Rescission Authority

The Working Group recommends “that CDRH consider issuing a regulation to define the scope, grounds, and appropriate procedures, including notice and an opportunity for a hearing, for the exercise of its authority to fully or partially rescind a 510(k) clearance. As part of this process, the Center should also consider whether additional authority is needed.” AACC supports this approach. The FDA should have clear, established authority to remove a device from the market if it endangers public safety. Additionally, it is important for manufacturers to understand what circumstances may trigger an agency action and what options are available for appeal.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC’s members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (919) 966-3724, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,



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