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Office of In Vitro Diagnostic Device Evaluation and Safety

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Overview of IVD Regulation

This section provides an overview of how FDA regulates IVDs. It does not operate to bind FDA or the Public. Manufacturers can find detailed information about complying with the Food, Drug and Cosmetic Act from the CDRH Regulatory Manuals website. For more information, see IVD Guidance Documents, IVD Standards, and IVD Advisory Panels.

What is an in vitro diagnostic product (IVD)?

What is a Premarket Approval (PMA)?

- A PMA is an application submitted to FDA to request approval to market, or continue marketing, a class III medical device.

- PMA approval is based on scientific evidence providing a reasonable assurance that the device is safe and effective for its intended use or uses. For IVDs, there is a unique link between safety and effectiveness since the safety of the device is not generally related to contact between the device and patient. For IVD products, the safety of the device relates to the impact of the device's performance, and in particular on the impact of false negative and false positive results, on patient health.

- FDA reviews PMA submissions in a 180-day timeline. If there are unaddressed scientific issues, the review scientists can ask for additional information and put the submission temporarily on hold. If a product is a first of a kind, or if it presents unusual issues of safety and effectiveness, it is generally reviewed before it is approved by an advisory panel of outside experts. Approval of a PMA requires review of the manufacturing processes, an inspection of the manufacturing facility, a bioresearch monitoring audit of clinical data sites, as well as comprehensive review of the premarket data.

- If FDA finds that a product is safe and effective, it receives an official approval order for marketing in the United States. If FDA finds that a product is not safe and effective, it may be non-approved.

- A manufacturer considering a PMA should consult 21 CFR 814.

Studies Required to Demonstrate Safety and Effectiveness

For most PMAs, sponsors identify surrogate endpoints and establish the device performance (clinical sensitivity and specificity or agreement) with relation to the identified endpoints in corollary studies using randomly collected clinical studies.

Limitations to FDA Review

There are several limitations to FDA's review of PMA applications:

- Lack of a "gold standard" against which to judge performance;
- Bias may occur in the collection of data to establish safety and effectiveness, through problems in the study design or conduct;
- It can be challenging to determine the minimum performance required for approval.

See also: