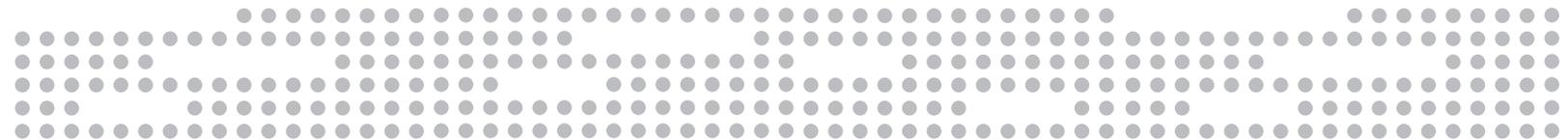




AN INFORMATIVE WHITE PAPER

# The Common Pitfalls of the Medical Device FDA Submission Process



**In 2011**, the FDA published a study\* that analyzed the review time for 510(k) submissions, and reported that 82% of all 510(k) submissions “contained at least one deficiency related to quality,” resulting in an action item letter.

The number of review cycles has grown from an average of 1.4 per submission in 2001 to 2.1 per submission in 2010. The percentage of submissions with at least one action item letter grew from 38% to 82% over the same time period. This report seeks to explain how to identify quality-related deficiencies, and how to avoid lengthy review cycles when attempting to move a medical device through the FDA approval process.

The following information, taken directly from the FDA’s report, defines a poor quality submission “as having at least one of the following deficiency categories”:

#### **Inadequate device description**

Every 510(k) submission is required to have a description of what the device is intended to do. Without this description, the reviewer cannot determine if the device has been evaluated properly by the sponsor. In other words, if the reviewer can’t tell from the submission what the device does, he or she cannot determine if the documentation included in the submission supports the device’s intended use. Therefore, it is essential that a thorough and clear description of the device be provided. Without it, a substantive review of the submission cannot be performed.

#### **Discrepancies throughout submission**

Discrepancies in this category most often related to device description or indications for use. Differences in device description can have a substantial impact on the review of a device because, under the 510(k) pathway, the intended use and technological characteristics of the new device are compared to that of a predicate device. When the indications for use statement is inconsistent in different parts of a submission (e.g., cover letter, indications for use form, 510(k) summary, device labeling have a different indications for use statements), we cannot determine if the device has the same indications for use as a predicate or if any differences alter the intended therapeutic/diagnostic effect of the device when compared to the predicate. Therefore, discrepancies preclude substantive review of a submission and require clarification.

#### **Problems with indications for use**

In order to be found substantially equivalent, a device must either have the same indications for use as a device already on the market (“predicate”

device), or any differences in the indications for use between the device and the predicate must not alter the intended use (i.e., the device's intended therapeutic/diagnostic effect). Furthermore, the type of performance data necessary to assess equivalence is dependent upon the indications sought. Therefore, a clear indications for use statement is necessary to determine if the methods used to evaluate the device accurately reflect its intended use. Quality issues related to indications for use include: lack of identification of any predicate for the indication, the indication requires a Premarket Approval (PMA) and for which a PMA already has been approved, the indication for use for a device that uses a drug is inconsistent with the drug labeling.

### **Failure to follow or otherwise address current guidance document(s) or recognized standards**

FDA issues guidance documents or recognizes a national or international standard to help manufacturers determine what information to include in a 510(k) submission generally, and for certain device types specifically. If a manufacturer fails to follow current guidance (i.e. that which is up-to-date) for a certain device type or a recognized standard, and offers no explanation for its failure to do so, FDA would consider that submission to be of poor quality and would issue an AI Letter that quotes current guidance to obtain the missing information. For our analysis we only determined that a submission had this deficiency if the AI Letter cited or quoted a guidance document.

### **Performance testing required for certain device types is completely missing (i.e., no performance data provided)**

Performance testing is required for all traditional 510(k)s. Because concerns with the adequacy of the testing provided in 510(k) submissions can pertain to the adequacy of the science, for our analysis, we only determined that a submission had this deficiency if no performance testing information was provided at all. Without performance testing, we cannot evaluate whether a device's performance is substantially equivalent to that of a predicate.

### **Clinical data required for certain device types is completely missing (i.e., no clinical data provided at all)**

For some device types, FDA requires clinical performance data to demonstrate substantial equivalence. FDA considers a submission to be of poor quality when such testing is clearly outlined in a device-specific guidance document or in a pre-IDE, but is completely omitted from a 510(k) submission. We did not consider it a deficiency if some clinical data, though inadequate, was provided.

As a company that provides design, development and test services for medical devices, Sterling Medical Devices has helped many clients navigate the rigorous FDA approval process and prepare their FDA submissions. What's more, we are frequently contacted by companies who made a submission without our help and who were rejected for at least one element of what the FDA defines as poor quality. Upon the companies' requests to assist with remediation, Sterling has identified and successfully remediated each of the areas of poor quality as described by the FDA report.

In addition to the issues cited by the FDA, our experienced team has the know-how to identify and address the following situations:

### **Submissions containing unneeded information**

Companies often try to make sure they have all bases covered by flooding the reviewer with documents and by putting more information than what is required by regulations into their submissions. Although this may be well-intentioned, remember that the FDA reviewer is required to review all documents submitted. By submitting unneeded information, it takes more time for the reviewer to complete their review, and the likelihood is increased that inconsistent information was provided. The general rule is to supply only the information required by regulations.

### **Unorganized submission and/or documents**

We recommend structuring your submission so that each section is clearly marked to refer to its corresponding regulation. We also recommend the same approach for all supporting documents (plans, requirements, reports, etc.).

### **Incomplete or unavailable risk planning documents**

The FDA is focused on patient safety. Therefore, risk planning documents are likely to receive extra attention from the reviewer. It is critical to have these documents properly prepared and completed.

### **Unclear test reports**

The FDA pays special attention to test reports. Difficult to understand background information and complicated rationale on any issues found during formal testing are common issues for test reports.

Quality-related deficiencies extend the approval process. Experience counts: Get the right help preparing your documentation in order to avoid time-consuming inquiries and ensure better time to market.

Reference:

\*Analysis of Premarket Review Times Under the 510(k) Program, Center for Devices and Radiological Health, U.S. Food and Drug Administration:

[www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm263385.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm263385.htm)



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