CASE STUDY

Lessons learned from missing the mark with FDA hot buttons

A surgical device manufacturer pursued their first 510(k) clearance for their CE-Marked product but was faced with considerable challenges during the FDA review process.

The client's challenge

Unfamiliarity with the 510(k) clearance process and working with the FDA cost this device manufacturer significant time and resources and produced only frustration. An initial 510(k) submission generated deficiencies from the FDA that could not be addressed during multiple rounds of questions and requests for additional information. Due to a lack of alignment between the FDA's expectations regarding the data and testing approach, the manufacturer had to withdraw the submission.

The Fortrea approach

The Fortrea team was experienced with similar devices and used this knowledge to evaluate the entire submission package, along with the deficiencies issued by the FDA, to identify weaknesses and gaps in the information. An analysis of the preclinical evidence generated by a contract animal testing laboratory identified inadequate controls and reporting procedures that (along with other testing anomalies) ultimately had caused the FDA to issue deficiencies across multiple areas within the submission package.

By working with the team to clarify the FDA expectations, address testing deficiencies and determine how existing animal study data could be leveraged, a comprehensive plan to rescue existing animal study data was developed, including a histologic reanalysis by an independent expert.

The Fortrea team worked with the manufacturer to interface directly with the FDA and gain buy-in on the leveraged data plan. By working with the FDA on the deficiencies identified, the team was able to address the client's issues and achieve the evidence required in order to provide substantial equivalence to the legally marketed predicate.

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The outcome

After two 510(k) submissions, several years of interaction with the FDA and a full reanalysis of the animal study histology data, clearance to market the device in the U.S. was successfully achieved.

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