



## Case Study:

# Guiding 510(k) Preparation and Submission for U.S. Medical Device Market Clearance

From late 2022 continuing through the publication of this case study in mid-2023, The FDA Group has been pleased to support a European biomedical sensor company's (Company) FDA premarket notification via the 510(k) pathway.

This project has primarily involved:

- Identifying, analyzing, and documenting numerous product modifications
- Redirecting the regulatory strategy from the Special 510(k) to the Traditional 510(k) submission pathway
- Providing regulatory mentorship and consultancy in navigating the intricacies of submission development

A small regulatory consultant team, sourced and managed by The FDA Group, has played a crucial role throughout the project's planning and execution phases. These professionals have presented the Company with an efficient, cost-effective model for project support that has helped bypass the administrative costs and practical burdens typically associated with managing such a project completely in-house.



## **The Problem**

The Company, acknowledging the complexity of the 510(k) pathway and the need for specialized expertise in handling what was uncovered to be a larger-than-expected number of modifications to their medical device, sought external regulatory assistance in cataloging these changes, crafting a revised regulatory strategy, and navigating the submission process.

The Company initially anticipated qualifying for the Special 510(k) pathway with just a few device changes. However, after a detailed examination by The FDA Group, over 100 modifications were discovered. The modifications included mechanical and software changes, re-validation of sterility, the addition of a component requiring a new biocompatibility assessment, additional EMC testing, and human factors testing.

## **The FDA Group's Approach & Solution**

Acknowledging the many multifaceted device modifications, The FDA Group recommended a strategic transition from the Special 510(k) to the Traditional 510(k) pathway. This decision was a proactive measure to avoid the risk of the FDA triggering a conversion due to extensive changes in the device, which surpass the scope of a Special 510(k) submission.

While the appeal of a Special 510(k) lies in its expedited review process, pursuing this pathway could have potentially compromised the thoroughness of the Company's submission, considering the substantial modifications made to the device and the absence of comparable data, especially given the new requirements added since the device's initial clearance.

The FDA Group determined that a Traditional 510(k) submission, although seemingly more time-consuming, would save the Company in the long run by eliminating the risk of potential delays caused by a mid-process conversion by the FDA. This approach will ensure comprehensive reports covering all general safety and performance requirements are submitted right from the start, aligning with current regulations.



While the submission will maintain some semblances to a Special 510(k) submission (as a modification of their device), it will ultimately be submitted under the Traditional pathway with full test reports.

To date, the revised submission strategy has involved a joint effort between the Company's in-house regulatory team and The FDA Group's consultants to:

- Catalog, analyze, and precisely classify all device modifications
- Determine which specific skillsets were necessary to compile the requisite documentation
- Assign roles to address the extensive documentation needs
- Assist and provide guidance in compiling necessary documentation and constructing the 510(k) submission

The FDA Group's team has served as regulatory advisors throughout this process, guiding the in-house regulatory team to undertake the bulk of the documentation and research required for each of the changes. To manage these many modifications, all changes were meticulously organized into a spreadsheet and individually assessed using the FDA's guidance flow charts. This ensured a comprehensive understanding and preparation for the eventual submission. The FDA Group has continued supporting the in-house regulatory team in gathering the necessary data and additional documentation required for the new submission.

Currently, one of the primary focus areas is Human Factors Engineering (HFE). The FDA Group provided the company with an HFE worksheet to detail the interactions between the device and its users. Once sufficient details are obtained, a test protocol will be developed to address the critical tasks identified.

For the next stage of the project, The FDA Group plans to present the Company's clinical trial data related to their claims, HFE proof, and sampling plans for validation studies as Q-Submission (Q-Sub) topics. This is to gain verification and concurrence on the planned submission strategy, specifically concerning identifying samples, sampling plans for validating safety and performance, and new anatomical site use claims for the device. The Q-Sub will also incorporate plans regarding the post-transit study samples used to validate performance, accessory concerns, sterility validation claims, and the biocompatibility report.



If the FDA finds the level of detail satisfactory during the Q-Sub, it will likely approve these plans and/or offer advice to adjust them. If there isn't enough data or detailed information, the agency will likely require another Q-Sub to be submitted before proceeding with testing and drafting the final submission.

## ***Results to Date and Ongoing Work***

By deploying the expertise and strategic thinking of The FDA Group through its project-based regulatory consulting model, the Company was successfully redirected to follow the Traditional 510(k) submission pathway, saving it from expensive and time-consuming setbacks and increased scrutiny from the FDA if the Special 510(k) pathway was pursued.

Leveraging the consulting team's prior FDA experience and familiarity with the 510(k) pathway, The FDA Group was able to quickly establish an understanding of the project and direct it toward its goals without further delays. While the project is still ongoing at the time of writing this case study, all external resources assigned have remained committed throughout the engagement, with zero turnover.

Upon completion of the current development phase, The FDA Group plans to continue working with the Company through the rest of the 510(k) submission and into post-market surveillance activities as the project progresses. This process is expected to extend through a significant part of 2023, if not longer.

## ***Impressions & Feedback***

The Company's leadership has consistently praised The FDA Group for its depth of knowledge, professionalism, and adaptability in adjusting to the unexpected challenges in their 510(k) submission. The Company has praised The FDA Group for its effectiveness in understanding the Company's unique requirements, quickly stepping in and establishing familiarity with the complex situation, and leading the redirection of the strategy. The continued success of this relationship will be crucial as the Company plans to submit additional 510(k)s in the near future.

