ACCELERATED

Regulatory Affairs + Human Factors Teams Support Safe and Efficient FDA Clearance for Surgical Device

A leading surgical device manufacturer enlisted our help to navigate and streamline a Class II FDA clearance process.

Client

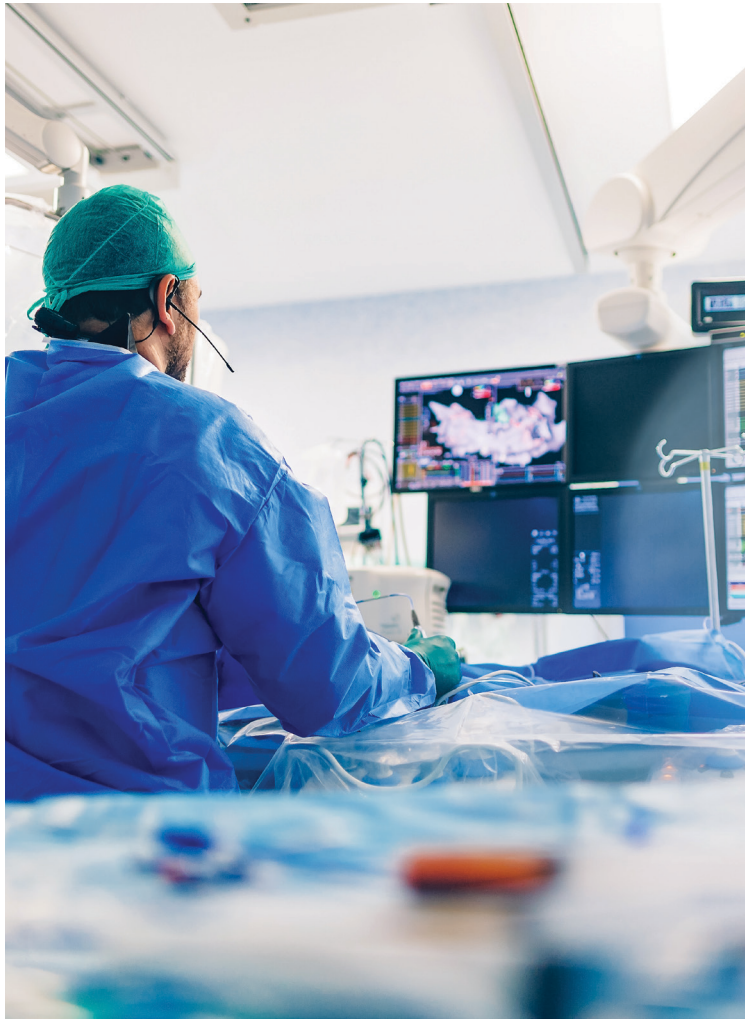
Surgical Device Manufacturer

Mission

Provide regulatory guidance, FDA submission support and human factors research support for a new cardiac catheter product

Outcome

Faster, more efficient FDA clearance process



A leading surgical device manufacturer and past Kaleidoscope Innovation client enlisted our help to navigate and streamline a Class II FDA clearance process for the improved design of a new cardiac catheter. The device, which allows access for diagnosis and treatment of heart and blood vessel procedures, was an innovative medical device that combined and integrated the functionality of two different products currently on the market, **a development that would allow for a more effective application, and ultimately, better patient outcomes.**

Though the end goal of the project was to provide the client with a 510(k) submission for FDA clearance, the work involved close coordination between Kaleidoscope's Regulatory Affairs and Human Factors teams.

Outlining Critical Tasks

The Regulatory Affairs team started the project by outlining a regulatory strategy and timeline, identifying the path forward, and developing the documentation required to support a substantial equivalence claim.

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Kaleidoscope® Innovation
Regulatory Affairs

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Once the need for Human Factors support was identified, that team got to work drafting the protocols and identifying two predicate devices currently in widespread use. These would be the models on which the documentation for both the safety and efficacy of the new product would be based. Often when Kaleidoscope supports FDA clearance, the predicate device is the client's previous version; in this case, the device predicates were products from two different competitors.

When it comes to medical products, human factors research requires a series of actions and deliverables that must be performed to demonstrate to the FDA that the proper design controls are in place, as well as mitigations for use-related risks for both the surgeon and the patient. To this end, Kaleidoscope's Human Factors team, along with the client's subject matter experts, conducted a use-related risk analysis to identify critical tasks that would inform the development of the human factors/usability engineering validation test protocol.

Implementing FDA Feedback

After an FDA Q Submission (i.e., pre-submission) meeting to align on the testing plan, the FDA provided their feedback along with guidance on the data required for the 510(k) submission. Our team also consulted on the selection of a simulator that could be used to effectively simulate how the catheter would work through what is called the "tortuous path" of blood vessels from the wrist to the heart in a live patient. Throughout the process, the Human Factors team supplied our Regulatory Affairs team with the detailed documentation needed to complete the 510(k) submission.

Achieving FDA Clearance

A project like this, moving through Human Factors testing through final FDA submission would take several months. Kaleidoscope and the client are in the final stages of compiling the documentation required for FDA 510(k) submission. Kaleidoscope will support the client throughout the FDA review process until the FDA grants marketing clearance, which is the last hurdle needed to bring the product to market.

Having Kaleidoscope's support at these critical junctures in product development not only accelerated the process, it also freed the client's internal resources so their team could focus on the company's other priorities.

The close and productive relationship with this client started in 2021 and continues to grow as their product development and other initiatives evolve.