CASE STUDY

Avoiding Market Access Delay Due to Incorrect Product Classification

A startup company (with the help of two innovative physicians) developed a tool that provides a safer, more effective way to alleviate a common orthopedic condition. Although early funding came at a cadence that kept progress moving steadily ahead, rounds for managing the entire life cycle to reach commercial distribution were relatively small. But by correctly classifying the device, time to market was minimized.

The Client's Challenge

The company had no staff that was acquainted with FDA regulations regarding medical device submissions. It initially assumed that, because of the invasive nature of the product, it had to be a Class II device and would therefore require a 510(k).

The Labcorp Approach

A Labcorp senior principal advisor took the time to integrate into the client's team in order to identify both the technology and business goals. Starting with the critical questions "why" and "how," Labcorp identified a new strategic approach. First, a Class I predicate was identified and a regulatory strategy was developed.

Then, a pre-submission package was prepared to allay regulatory strategy concerns from the board of directors and to demonstrate the feasibility of the concept. After a successful FDA interaction, Labcorp consultants further helped manage an iterative and interactive pathway to complete the design process and design validation.

The final step was to design a CFR 820 compliant quality system addressing the unique needs of supplier management and complaint handling in a virtual company. This approach kept the overhead burden down while at the same time providing a solid launch pad for future growth.

The Outcome

The client was able to enter market faster and with less expense by using a regulatory strategy and data-supporting registration and then listing as a Class I device. While typical concept-to-bedside timelines for devices can vary anywhere from 18 months to eight years, by carefully examining the requirements for Class I devices, the company was able to gain FDA agreement that the device was a Class I, requiring only general controls.

This strategy optimized the development pathway and successfully avoided many preclinical and clinical costs. From concept to market the product was in the hands of physicians within two and a half years. At the same time, the company's quality control system and selection of vendors has ensured compliance with FDA design controls and all regulatory responsibilities.

Learn more at medtech.labcorp.com

labcorp

Originally authored in 2020.
©2022 Laboratory Corporation of America® Holdings All rights reserved. CSDEV004-0122