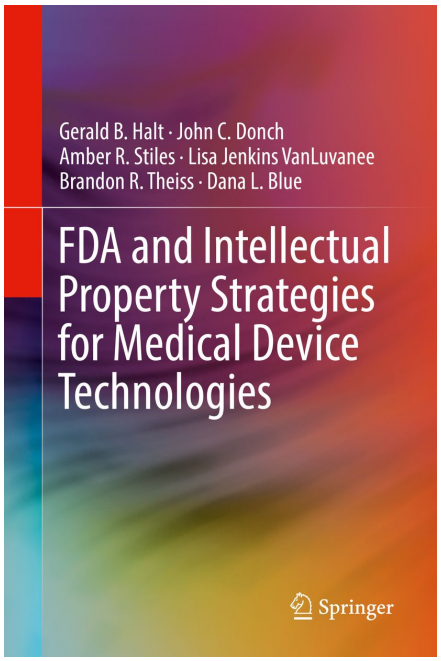

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FDA and Intellectual Property Strategies for Medical Device Technologies

- Investigates the FDA approval process as it pertains to medical device technology
- Address some of the major FDA hurdles that medical device innovators often face while seeking approval
- Discusses the interplay between FDA regulatory review of medical device technology and intellectual property strategy
- Explores the benefits of protecting, managing and enforcing intellectual property obtained for medical device technology so that innovators can obtain the best possible commercial results from their IP ownership
- Uses real case studies to illustrate concepts covered

This book offers comprehensive, easy to understand guidance for medical device technology innovators on how to work through the United States FDA regulatory review process, while also providing insight on the various intellectual property concerns that many medical device innovators face. In the first portion of this book, readers are introduced to important concepts concerning FDA compliance for medical devices, as well as strategies for successfully navigating the FDA regulatory review process. Specifically, the first portion discusses the expansive range of medical devices and then walks through the most common routes to market: the PMA and 510(k) application processes. In the second portion of this book, readers are introduced to the various types of intellectual property rights that are available for medical device technology inventions and innovations, and can explore ways to overcome unique intellectual property challenges faced by many medical device technology innovators.

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