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Nota di contenuto	Introduction -- Development of A New Medical Device -- Determining If A Medical Device Technology Is FDA Regulated -- Basic FDA Regulatory Requirements For Medical Devices -- Other Regulatory Consideration For Medical Devices -- Benefits of Having FDA Approval -- Patents -- Trademarks and Trade Dress -- Trade Secrets -- Copyrights In Medical Device Technology -- Design Protection For Medical Devices -- Intellectual Property Issues in Medical Device Labeling and Marketing -- Enforcement, Infringement and Monetization of Intellectual Property Rights -- Successful Implementation of a Medical Device Company’s IP Strategy -- Tips for Avoiding and Preventing Intellectual Property Problems -- Successful Implementation of a Medical Device Company’s Regulatory Strategy -- Tips for Avoiding and Preventing Regulatory Problems -- Potential Combined IP and Regulatory Pitfalls.

Sommario/riassunto

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. In the third portion of the book, specific strategies are discussed to navigate the interface between the FDA regulatory process and the process of obtaining intellectual property protection. This book also includes a number of descriptive examples, case studies and scenarios to illustrate the topics discussed, and is intended for use by medical device designers, developers and innovators. 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.