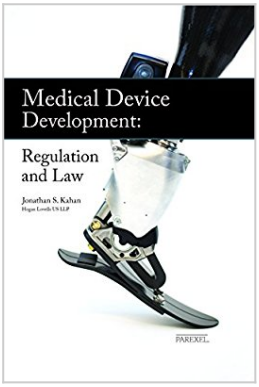

Medical Device Development: Regulation and Law

By Jonathan S. Kahan, Hogan Lovells US LLP

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Medical Device Development: Regulation and Law, 2014 Edition, is the "must-have" resource for the novice or veteran medical device regulatory affairs professional. This practical reference provides the most comprehensive and updated analysis of US medical device and diagnostics development and approval requirements anywhere. Since the 2009 edition of this book, new device legislation has been enacted and FDA has issued over a dozen or more important new guidances. The 2014 edition features in-depth analysis of these developments, and addresses how emerging developments and trends are reshaping medical device and combination product regulations in the US. The 2014 edition of this popular and authoritative resource reviews and analyzes the following critical developments since the 2009 edition: * Update on all the new provisions of the Food and Drug Administration Safety and Improvement Act of 2012 (FDASIA). * New statutory provisions and guidances related to device reclassification, humanitarian devices, the CDRH appeal process, Section 522 postmarket surveillance, and custom devices. * New statutory provisions and guidances related to mobile medical apps and medical device software, including medical data software systems. * Updates on the new organizational structure of CDRH, including revisions to the structure of the Office of Device Evaluation the Office of Compliance, and the Office of In Vitro Diagnostics and Radiological Health. * Changes to the 510(k) premarket notification process, including new policies on split predicates, when a device cannot be found to be SE, and the new priority review guidance. * Changes to the pre-submission process, including the end of the pre-IDE process and the birth of the Q-sub. * New guidances on FDA s Refusal to Accept policies relating to 510(k)s, PMA s, and pre-submissions. * Update on the investigational device exemption process, including new guidances on early feasibility studies, FDA decisions for IDE investigations, design considerations for pivotal clinical device investigations, and good laboratory practices. * Changes to the premarket approval application process, including birth of the e-copy and modifications to the advisory panel process. * New policies and guidances concerning in vitro diagnostic products, including the new guidances on Research Use Only (RUO)/Investigational Use Only (IUO) products, and in vitro companion diagnostics. * Update on device compliance issues, including the 2013 draft medical device reporting guidance

and recall procedures relating to product enhancements. * New guidances and cases relating to combination products incorporating medical devices.

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Editorial Review

Review
Great book for a beginner learning about process, or an experienced practitioner in the field. I used prior addition, until i realized it was updated - i testify on matters of value in the field of medical devices, and nothing helps the court understand faster - than a text book you can cite documenting the process of a 510(k) application or a PMA! --Richard Mackenzie, Amazon Verified Purchase

I recently acquired a copy of Jonathan Kahan s book entitled Medical Device Development: Regulation and Law, in its most recent edition. I have been in the regulatory affairs profession for over 23 years now, and can easily navigate websites and references to find the information I need. However, as I was reviewing a recent FDA proposed rule, I found myself repeatedly reaching out to the book as all the information I needed was compiled and easily found in one place, organized by topic, with all needed legislative and regulatory references. Mr. Kahan has done an admirable job in creating this book, and I am thankful to have it on my desk for easy reference when needed. --Tamima Itani, Ph.D., FRAPS, RAC MSVP, Global Regulatory Affairs and Regulatory Compliance, Boston Scientific

About the Author
The book is written by Jonathan S. Kahan, Partner, Hogan Lovells US LLP in Washington, D.C. Jon is a co-director of the firm s food, drug, medical device, and agriculture group, and has been practicing in FDA law for 40 years. Jon is also an Adjunct Professor at the George Washington University Law School teaching medical device law. His practice focuses primarily on assisting medical device companies in navigating the U.S. Food and Drug Administration (FDA) regulatory process. He also has an extensive practice in combination products, which includes combinations of drugs, devices, and biologics. In addition to the daily counseling of clients in FDA-related matters, he represents many clients in administrative hearings and trials, and in the federal courts. Jon has published numerous law review and other articles concerning FDA regulatory issues.

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