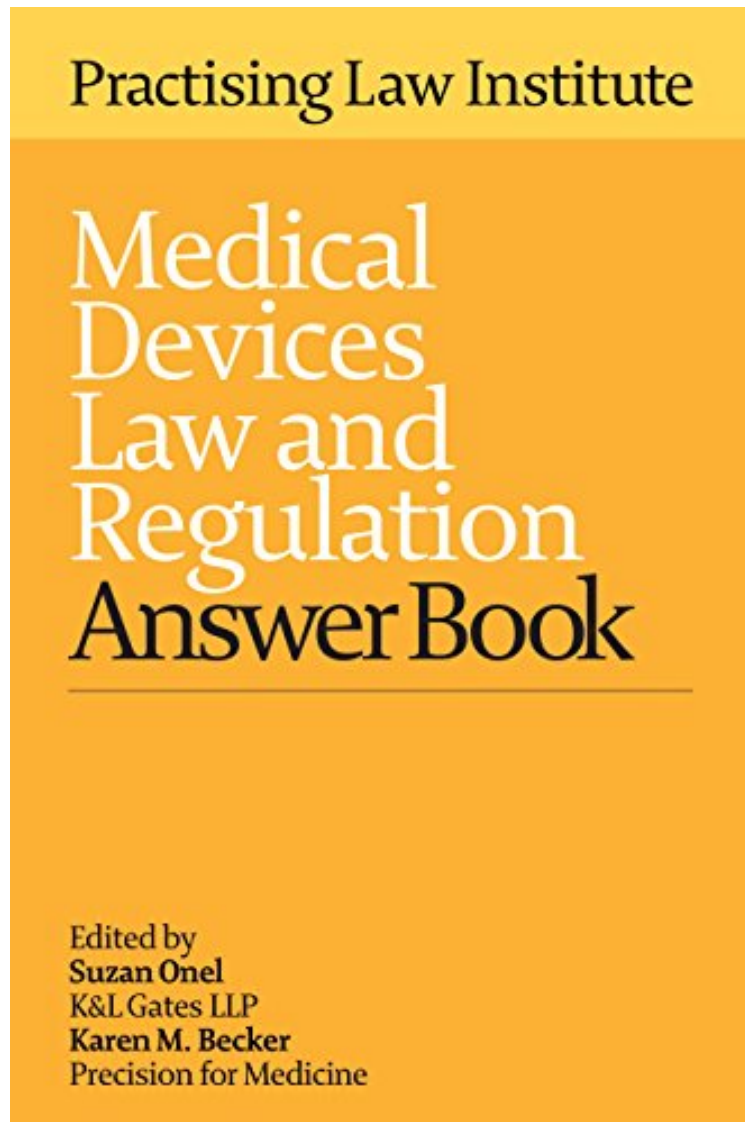


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The regulation of medical devices has grown increasingly complex since the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (FDCA) were introduced in 1976. Medical Devices Law and Regulation

Answer Book 2015 walks you through the current regulatory requirements and describes every aspect from pre-market requirements for specific types of devices to post-market regulation and ongoing government enforcement and investigation. With over 30 contributors from a variety of major law firms and consulting firms specializing in medical device work, Medical Devices Law and Regulation Answer Book 2015 provides practical guidance on how to handle every day questions on a wide variety of topics as well as what issues are likely to arise and how to avoid them. The breadth of coverage of this new publication is illustrated by the chapter titles provided below: Overview of Medical Device Regulation in the U.S. Clinical Studies of Investigational Devices Device Premarket Submissions Devices with Unique Issues Combination Devices, Radiological Devices, Restricted Devices, Customer Devices, Device Software In Vitro Diagnostic (IVD) Devices The Quality System Regulation Device Facility Inspections Post Market Considerations International Considerations Enforcement and Government Investigations Regarding Medical Devices Interacting with FDA Intellectual Property Considerations for Medical Device Companies Fraudulent and Abusive Practices in the Reimbursement for Medical Devices HIPAA s Impact on the Medical Device Manufacturing Community Continuing Medical Education (CME) and Industry-Supported Scientific Activities Litigation, Product Liability, and Preemption Licensing, Product Development and Commercialization FDA Criminal Enforcement Overlapping Jurisdiction with other Agencies and Law Enforcement Entities Commonly Used Acronyms