



Medical Device Development: Regulation and Law

By Jonathan S. Kahan

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Medical Device Development: Regulation and Law, 2nd 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. This book also features in-depth analysis on how emerging developments and trends are reshaping medical device and combination product regulations in the US. The second edition of this popular and authoritative resource addresses the latest regulatory and legal developments that guide how medical devices are developed today: * The Medical Device User Fee and Modernization Act of 2002, including user fees, third party inspections, reprocessed single use devices, and the establishment of the Office of Combination Products. * The Food and Drug Administration Amendments Act of 2007, including unique device identifiers, ClinicalTrials.gov registration, pediatric device promotion, and postmarket surveillance and medical device reporting changes. * The current and future landscape of electronic 510(k) and PMA submissions. New chapters and features in the second edition include: * Medical Device Compliance and Postmarket Surveillance requirements. * Quality System Regulation, including management controls, design controls, risk analysis and corrective and preventive action, and other QSR provisions. * In Vitro Diagnostics, including IVD clinical studies, ASR regulation, LDTs, CLIA, and IUO/RUO requirements. * Combination Products and Product Jurisdiction, including a description of FDA's jurisdictional decision-making for single entity products, the establishment of the Office of Combination Products and its jurisdiction and processes, with a detailed discussion of the new definition of the primary mode of action. * A glossary and comprehensive index of terms and concepts.

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Editorial Review

About the Author

Jonathan S. Kahan, Partner, Hogan & Hartson LLP in Washington, D.C., is a co-director of the firm's food, drug, medical device, and agriculture group. Jonathan has been practicing in FDA law for 35 years. 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. Jonathan has published numerous law review and other articles concerning FDA regulatory issues.

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