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Medical Device Development: Regulation and Law

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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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