Medical Device and Radiation Emitting Products Regulation (Food and Drug Law Book 4)

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Did you know that medical devices were originally regulated under the United States Postal Statutes? That changed with enactment of the United States Food, Drug and Cosmetic Act. Thousands of types of medical devices exist in the market today, ranging from a simple tongue depressor to a more complex pacemaker. The Center for Devices and Radiological Health (CDRH) regulates medical devices. The goals of this volume are to: discuss the historical foundation for medical device legislation as well as current pertinent legislation; provide examples of specific device classifications; provide information about medical device fundamentals, types of submissions, liability, preemption, postmarket surveillance and enforcement mechanisms. Landmark cases involving the legal concept of preemption are included as well. Preemption is a legal term of art that emanates from the Supremacy Clause (Article VI, clause 2) of the United States Constitution. Article VI, clause 2 prohibits states from enacting laws that conflict with federal law unless the federal law contains explicit preemption language. Each chapter contains critical analysis issues to explore.

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