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System (NEISS) and medical devices; Description and history of NEISS; Potential uses and limitations of NEISS
Utilization of NEISS to produce national medical device-associated adverse event estimatesPotential for long-term utilization of NEISS for medical device surveillance; 7 Medical device nomenclature; Technical elements; Current terminologies; Applications of nomenclature; Future developments; 8 Data sources for medical device epidemiology studies and data mining; Introduction; Data sources; Surveillance databases; Registries; Automated large administrative databases; National surveys; Data mining; Future use databases for medical device epidemiology
9 Ethical requirements and guidelines for epidemiological studiesof medical devicesIntroduction; Bioethics foundations; US government human subjects protection regulations; HHS human subjects protection regulatory requirements; FDA human subjects protection regulations; Other professional ethical guidelines; Ethical requirements for medical devices epidemiologic studies; Future ethical requirements for epidemiologic studies; 10 An industry perspective: medical device epidemiology and surveillance; Introduction
The product's life cycle: premarket (preclinical and clinical) and postmarket (PM) studiesPostmarket studies; Summary; 11 Perspective from an academic on postmarket surveillance; Introduction; Adverse event reporting; Postmarket condition of approval studies and Section 522 studies; Industry use of information from adverse event reports; Academic opportunities; Summary; 12 Perspective from a pharmacoepidemiologist; Introduction; Review of literature; Contrasts with pharmacopeidemiology; Conclusions; 13 Medical device regulation and surveillance: perspective from the EU; Introduction
Medical devices: the European directives and definitions

Sommario/riassunto

Medical devices are crucial in medical care today and device technology advances at a dizzying pace. Medical Device Epidemiology and Surveillance is the first book to provide an overview of medical device epidemiology and surveillance as well as perspectives from regulatory agencies, the medical device industry, the health insurance industry and academia. The book is edited by experts from the US Food and Drug Administration with contributions from experienced specialists working in this field in the US and around the world. It features chapters describing broad themes in medical