1. Record Nr. UNISA990002158590203316

Titolo	L'Europa tra integrazione economica ed egemonia politica / [scritti di] Lelio Basso ... [et al.]
Pubbl/distr/stampa	Milano : Angeli, 1979
Descrizione fisica	153 p. ; 22 cm
Collana	Quaderni di Problemi del socialismo ; 11
Disciplina	337.142
Soggetti	Movimento operaio
Collocazione	337.142 EUR 4 (Coll. APY 11) 337.142 EUR 4 a (Coll. APY 11)
Lingua di pubblicazione	Italiano
Formato	Materiale a stampa
Livello bibliografico	Monografia

2. Record Nr. UNINA9910781521303321

Titolo	Medical devices and the public's health [[electronic resource]] : the FDA 510(k) clearance process at 35 years / / Institute of Medicine of the National Academies
Pubbl/distr/stampa	Washington, D.C., : National Academies Press, 2011
ISBN	0-309-21245-6 1-283-37627-X 9786613376275 0-309-21243-X
Descrizione fisica	1 online resource (280 p.)
Disciplina	363.19
Soggetti	Medical instruments and apparatus - Safety regulations - United States Medical instruments and apparatus - Standards - United States Medical instruments and apparatus - Law and legislation - United States Public health - United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa

Livello bibliografico	Monografia
Note generali	"Committee on the Public Health Effectiveness of the FDA 501(k) Clearance Process, Board on Population Health and Public Health Practice."
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	""Front Matter""; ""Reviewers""; ""Acknowledgments""; ""Preface""; ""Contents""; ""Boxes, Figures, and Tables""; ""Acronyms and Abbreviations""; ""Summary""; ""1 Introduction""; ""2 Key Medical-Device Legislative and Regulatory Actions""; ""3 Components of US Medical-Device Regulation""; ""4 The 510(k) Clearance Process""; ""5 Postmarketing Surveillance, Compliance, and Enforcement""; ""6 External Factors That Affect the Medical-Device Regulatory System""; ""7 Conclusions and Recommendations""; ""Appendix A: History of Medical-Device Legislation and Regulation in the United States"" ""Appendix B: Committee Biographies""""""Index""
Sommario/riassunto	"Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical devices and the public's health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical devices and the public's health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework"--Publisher's description.