

1. Record Nr.	UNINA9910457208603321
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	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 Electronic books.
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""

2. Record Nr.	UNINA9910964130403321
Titolo	Safe passage : astronaut care for exploration missions // John R. Ball and Charles H. Evans, Jr., editors ; Committee on Creating a Vision for Space Medicine during Travel Beyond Earth Orbit, Board on Health Sciences Policy, Institute of Medicine
Pubbl/distr/stampa	Washington, D.C., : National Academy Press, c2001
ISBN	9780309170314 0309170311 9780309500098 0309500095
Edizione	[1st ed.]
Descrizione fisica	1 online resource (318 p.)
Altri autori (Persone)	BallJohn <1944-> EvansCharles H <1940-> (Charles Hawes)
Disciplina	616.9/80214
Soggetti	Astronauts - Health and hygiene Space medicine
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Bibliographic Level Mode of Issuance: Monograph
Nota di bibliografia	Includes bibliographical references (p. 221-243) and index.
Nota di contenuto	Cover -- Front Matter -- Reviewers -- Foreword -- Preface -- Acronyms -- Contents -- LIST OF BOXES, FIGURES, AND TABLES -- Executive Summary -- 1 Astronaut Health Beyond Earth Orbit -- 2 Risks to Astronaut Health During Space Travel -- 3 Managing Risks to Astronaut Health -- 4 Emergency and Continuing Care -- 5 Behavioral Health and Performance -- 6 Exploring the Ethics of Space Medicine -- 7 Planning an Infrastructure for Astronaut Health Care -- References -- APPENDIXES -- A Background and Methodology -- B Committee and Staff Biographies -- Index.
Sommario/riassunto	Safe Passage: Astronaut Care for Exploration Missions sets forth a vision for space medicine as it applies to deep space voyage. As space missions increase in duration from months to years and extend well beyond Earth's orbit, so will the attendant risks of working in these extreme and isolated environmental conditions. Hazards to astronaut health range from greater radiation exposure and loss of bone and muscle density to intensified psychological stress from living with

others in a confined space. Going beyond the body of biomedical research, the report examines existing space medicine clinical and behavioral research and health care data and the policies attendant to them. It describes why not enough is known today about the dangers of prolonged travel to enable humans to venture into deep space in a safe and sane manner. The report makes a number of recommendations concerning NASA's structure for clinical and behavioral research, on the need for a comprehensive astronaut health care system and on an approach to communicating health and safety risks to astronauts, their families, and the public.
