

1. Record Nr.	UNINA9910698835203321
Titolo	Premarket approval application modular review [[electronic resource]]
Pubbl/distr/stampa	Rockville, MD : , : U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health : , : Center for Biologics Evaluation and Research, , [2003]
Descrizione fisica	14 pages : digital, PDF file
Soggetti	Medical instruments and apparatus - Evaluation - Government policy - United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Title from PDF title page (viewed on May 22, 2009). "Document issued on: November 3, 2003". "Supersedes and replaces " A modular approach to PMA review ", dated January 29, 1998, and "Guidance for the medical device industry on PMA shell development and modular review", dated November 6, 1998".