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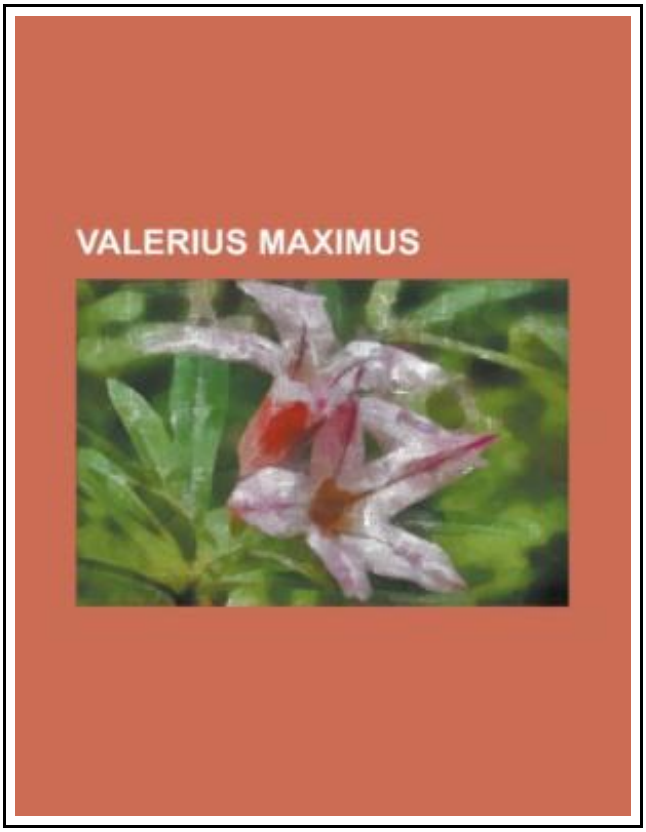

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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 38 pages. Original publisher: Washington, D. C. (P. O. Box 37050, Washington 20013) : U. S. General Accounting Office, 1998 OCLC Number: ocm41979315 Subject: Medical instruments and apparatus -- Safety regulations -- United States. Excerpt: . . . B-280391 FDA officials acknowledged that changes are needed to better assess FDA Plans to Redirect compliance with the medical device tracking regulation and improve its Inspections and Change Its oversight of manufacturers subject to tracking. For example, FDA has Audit Approach Toward included in its fiscal year 1999 performance plan a risk-based inspection High-Risk Device plan that will require FDA to identify and prioritize device areas of concern Manufacturers to focus resources on the highest priorities. Inspection activities would be prioritized based on several factors, including reports of problems with medical devices, earlier inspections, and devices associated with higher risk. officials told us that many of the devices designated for tracking, FDA such as cardiovascular implants, would likely receive priority attention because of the relative high risk associated with their use. The risk-based FDA plan is expected to be presented to s Medical Device Field Committee, which is responsible for reviewing and approving significant changes to on-site inspections before they can be included in s compliance FDA program. FDA To improve s assessment of manufacturer compliance with tracking requirements, officials of the Office of Compliance told us they are GMP considering separating inspections of manufacturing and distribution processes from records inspections - which typically include reviews of manufacturer compliance with medical device reporting and tracking requirements under SMDA 90 - thereby allowing inspectors more time to review manufacturer compliance with recordkeeping requirements. In addition, the Office of Compliance also plans to develop an audit plan that will require inspectors to...

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