The
New 510(k)
Paradigm

Alternate Approaches
to Demonstrating Substantial Equivalence
in Premarket Notifications

Final Guidance

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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March 20, 1998

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Preface

As part of the Center for Devices and Radiological Health's (CDRH) organizational transformation initiative, the 510(k) Process Reengineering Team examined the existing process through which regulated industry demonstrates substantial equivalence of medical devices in premarket notifications (510(k)s). On June 13, 1997, the Food and Drug Administration (FDA) released a draft proposal entitled, "A New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" for comment on the Internet. The proposal was the subject of two videoconferences which were co-sponsored by FDA and the Food and Drug Law Institute (FDLI) and was also discussed at several trade and industry association meetings. On September 19, 1997, the Agency published a Notice of Availability of the proposal in the Federal Register (62 FR 49247) to formally solicit comments from interested parties.

During this same period of time, the United States Congress was in the process of drafting the FDA Modernization Act of 1997 (the FDAMA)(Pub. L. 105-115), which amended the device provisions of the Federal Food, Drug, and Cosmetic Act (the Act). During its deliberations over the new law, several of the concepts in the New 510(k) Paradigm were discussed by members of Congress. On November 21, 1997, the President of the United States signed into law the FDAMA, which incorporated many of the changes proposed in the New Paradigm as well as many others that were envisioned in the Center's reengineering efforts. As a direct result of the enactment of this new law and the comments that were received during the period of public review, the 510(k) Process Reengineering Team developed this final guidance document.

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