



**Medtronic**

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March 22, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 10-61  
Rockville, MD 20852

Re: Proposed Rule on Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification (Docket No. 99N-4784)

Dear Sir or Madam:

Medtronic, Inc submits the following comments in response to FDA's notice announcing the availability of the "Proposed Rule on Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification" [Federal Register Volume 64, Number 244, December 21, 1999]. Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies that restore health, extend life, and alleviate pain. Medtronic, Inc.'s operations are primarily focused on providing therapeutic, diagnostic, and monitoring systems for cardiac rhythm management, cardiovascular, neurological, and spinal markets that in 1999 benefited over 1.5 million patients worldwide.

Medtronic, Inc. appreciates FDA's efforts to protect applicants from release of nonpublic information contained within premarket notification applications (510(k)) and is grateful for the opportunity to comment on this proposed rule. We support and are encouraged by FDA's attempts to reduce the agency's staff burden on non-product review activities, with the intention to redirect these resources to primary product review functions. However, we are concerned that the benefits achieved by the implementation of this proposed rule are disproportionate to the increased burden to 510(k) applicants.

Medtronic, Inc. believes that the FDA's current predislosure notification practice, in accordance with Executive Order 12600, sufficiently fulfills the Freedom of Information Act's (FOIA) requirement for public disclosure of 510(k) information. The addition of a requirement for an applicant to provide a redacted version of each 510(k) application places an additional burden on device manufacturers without demonstrating clear benefit.

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On the contrary, this proposed rule places increased regulatory burden on medical device manufacturers that does not match the historical demand for such information. It has been our experience that requests by the public for copies of released 510(k) applications has been very low, evidenced by the small numbers of FOIA requests received by our company each year to redact released 510(k)s.

The requirement for the submission of a 510(k) Summary or Statement has proven to be adequate to fulfill the majority of information requirements. In situations where additional information is required, the current system of predisclosure notification has proven to be effective. The FDA's proposed rule would require an increase in the amount of time and expense on the part of the applicant and the potential to relieve FDA staff to make them available to review new product applications is not certain.

In addition to our general concerns as stated above, Medtronic, Inc. requests that the FDA address the following deficiencies of this proposed rule:

#### Redaction of Confidential Information Contained Within Documentation Generated by the FDA

Under the current system, when the FDA provides a releasable 510(k) application to an applicant for redaction, the entire application is provided. This information includes documentation generated by the FDA. These documents typically include FDA internal summaries, checklists, and correspondences. Under the proposed rule, there is no mechanism defined for the FDA to provide and the applicant to review and redact confidential information that may be contained in such documents prior to release to the public. Predisclosure notification to the applicant of information generated by the FDA is still required and would need to be provided separately from submission of the redacted version generated by the applicant. Therefore, the intended benefits of the proposed system would be lost. The FDA would still be dependent on the current internal predisclosure notification system in providing the FDA generated documents to the applicant. Thus, the redacted 510(k) would be made available to the public within the same time frame as the current system provides.

#### Redundancy in Providing a Redacted 510(k) and 510(k) Summary or Statement

Medtronic, Inc. believes that if the requirement to submit a redacted 510(k) is adopted, this requirement makes the submission of a 510(k) Summary or Statement redundant, thus unnecessary. Because the complete original application (minus confidential and proprietary information) is provided in the redacted 510(k), there is no benefit to the public in receiving the information contained in a 510(k) Summary after a redacted 510(k) has been made available. Likewise, the availability of a redacted 510(k) makes the requirement of a 510(k) Statement unnecessary because the same information is included in both documents.

Identification of a Redacted 510(k)

Clarification is required as to how a redacted copy of a 510(k) is to be identified at the time of submission to assure appropriate processing within the FDA. Will the redacted version of the 510(k) be considered a Supplement to the original application? Does this proposed rule apply to "Special" and "Abbreviated" 510(k)? The identification and treatment of a redacted 510(k) must be clearly defined.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Medtronic, Inc.

A handwritten signature in cursive script, appearing to read "C. Whitacre".

Chip Whitacre  
Director, Corporate Regulatory and Clinical Affairs

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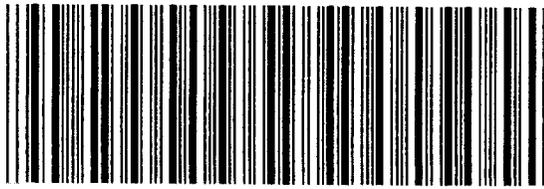
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