

**Boston  
Scientific**  
**SCIMED**

March 21, 2000

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Scimed Life Systems, Inc.  
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Maple Grove, MN 55311-1566  
612.494.1700  
www.bscl.com

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, room 1061  
Rockville, MD 20852

Re: Comments on "Premarket Notification; Requirement for Redacted Version of Substantially Equivalent Premarket Notification" [Docket No. 99N-4784]

Boston Scientific SCIMED, Inc. appreciates the opportunity to offer input on the proposed rule for 510(k) redaction and would like to submit the following comments:

1. It is our impression that only a small portion of submitted 510(k)s are requested through FOI. Requiring a manufacturer to submit a redacted version for each submission seems unduly burdensome.
2. Currently when FDA sends a submission file to the manufacturer for redaction, it often includes the reviewer notes and some internal FDA correspondence. There have been several cases where we redacted portions of the reviewer notes that referenced trade secret information. It would be a concern if the reviewer notes were sent out without the manufacturer's ability to redact certain information.
3. The proposed rule states that the current 5 day timeframe does not allow the manufacturers enough time to provide a redacted version of the submission. We do not believe that this is a major issue, since we have always had adequate time to provide the information.

Please contact the undersigned by phone (763-694-5582) or fax (763-694-5899) if you have any questions regarding this document.

Sincerely,



Melanie Raska  
Sr. Regulatory Affairs Specialist

99N-4784





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Sincerely,

A handwritten signature in cursive script that reads "Melanie Raska".

Melanie Raska  
Sr. Regulatory Affairs Specialist