

# HITACHI

## HITACHI MEDICAL SYSTEMS AMERICA, INC.

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December 22, 1999

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

Reference: 21 CFR 807, Docket No. 99N-4784  
Requirement for Redacted Version of Substantially-Equivalent Premarket  
Notification

Dear Sirs:

Thank you for the opportunity to comment on this Proposed Rule. We offer the following comments and questions to be addressed by the Agency:

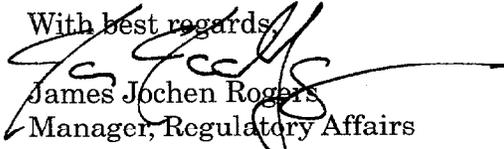
1.0 As a 510(k) holder, we receive a number of "predisclosure notifications" annually in accordance with Executive Order 12600, and we do our due diligence to provide an appropriately redacted 510(k) with reasons to support redaction. All predisclosure notifications that we have received contain Agency-internal documents, including but not limited to, routing slips, device reviewer memoranda, 510(k) "substantial equivalence" decision-making process flowcharts and documentation, device descriptions, summary descriptions of the 510(k), and telephone/telefax conversation/content summaries. These types of Agency-internal documents may additionally contain trade secret information that can (and have been) appropriately redacted. However, these documents also often provide useful information that is of value under FOIA.

How will the Agency handle these types of Agency-internal documents as part of this Proposed Rule? Will they be no longer made available as part of the final Pre-market Notification? Will the Agency provide them to the 510(k) holder as part of the Substantial Equivalent letter, with an instruction to "add these documents to your appropriate 510(k) files"?

- 2.0 The Final Rule should indicate that any and all FDA Request(s) for Additional Information (deficiency letters), and the 510(k) holder's responses to those requests, should be additionally included in the submitted redacted version of the substantially-equivalent premarket notification.
- 3.0 Will the 510(k) substantial equivalence letter to the 510(k) holder be revised to contain instructions and text that the recipient has an obligation to file a redacted version of the complete 510(k) premarket notification document with 30 days of receipt of 510(k) clearance?

We hope that these questions and comments are of value in your development of this Final Rule. If you have any questions, please feel free to contact us.

With best regards,

  
James Jochen Rogers  
Manager, Regulatory Affairs

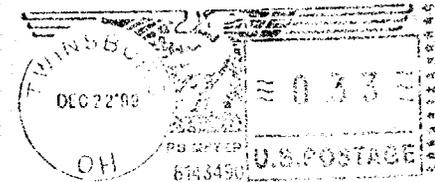
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