

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2006N-0362]

Display Date 5-7-07  
Publication Date 5-8-07  
Certifier J. P. [Signature]

*[Handwritten signature]*

**General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device; Reopening of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until *[insert date 30 days after date of publication in the Federal Register]*, the comment period for the proposed rule, published in the **Federal Register** of October 31, 2006 (71 FR 63278). The proposed rule would reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). FDA is taking this action in response to two requests for an extension of the comment period for this rulemaking. Elsewhere in this issue of the **Federal Register**, FDA is also reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

**DATES:** Submit written or electronic comments on the proposed rule by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** You may submit comments, identified by Docket No. 2006N-0362, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

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*2006N-0362*

*NEC 1*

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:

Division of Dockets Management (HFA–305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). FDA invited interested persons to comment on the proposed rule by January 29, 2007. Two companies requested FDA to extend the comment period by 90 days because the proposal presented complex medical and scientific issues that required the company to assemble a team of many different specialties in order to prepare their comments.

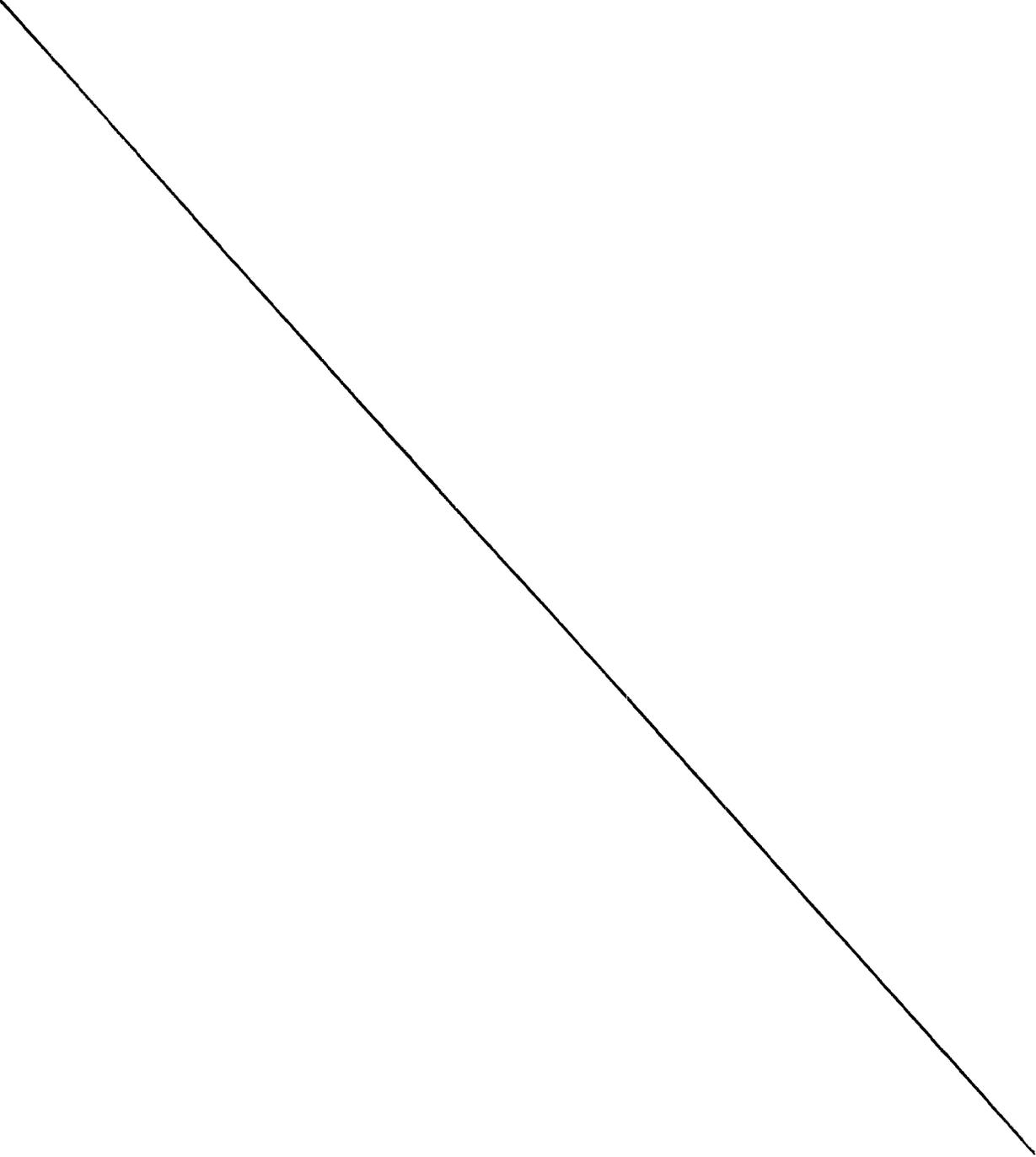
FDA was unable to respond to the request to extend the comment period before the comment period ended. Therefore, FDA is reopening the comment period for 30 days in order to allow the requestors and other interested persons to complete and prepare their comments. FDA believes that these 30 days in addition to the time that has already passed since the proposal was published allows for sufficient time for preparation of comments.

Elsewhere in this issue of the **Federal Register**, FDA is also reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed

comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 4/25/07  
April 25, 2007.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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