

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2007N-0267]


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**Medical Devices; General and Plastic Surgery Devices; Classification of
Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by
Recombinant DNA Technology**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant deoxyribonucleic acid (DNA) technology into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology." The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*]. The classification was effective February 8, 2007.

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FOR FURTHER INFORMATION CONTACT: Nada O. Hanafi, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3555.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying

the device, FDA will publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on November 7, 2005, classifying the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On May 12, 2006, after Tepha, Inc., had received CDRH's response to an April 7, 2006, appeal from the company, Tepha, Inc., submitted a petition under section 513(f)(2) of the act requesting classification of the device. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device type, absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology, can be classified into class II because special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish special controls to provide such assurance.

The device type is assigned the generic name, “absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology,” and is identified as an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant DNA technology. The device is intended for use in general soft tissue approximation and ligation.

FDA has identified the risks to health associated with this type of device as: Improper selection and use, suture breakage, adverse tissue reaction, and infection. The special control FDA is establishing is a special controls guidance document that FDA believes will aid in mitigating the potential risks to health, as described in table 1 of this document.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risk	Mitigation Measures
Improper selection and use	Physical and performance characteristics Biocompatibility Labeling
Suture breakage	Physical and performance characteristics Expiration dating
Adverse tissue reaction (i.e., irritation, inflammation, immune response)	Biocompatibility
Infection	Sterility

FDA believes that special controls, in addition to general controls, address the risks to health identified above and provide reasonable assurances of the safety and effectiveness of the device type. Thus, on February 8, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification at 21 CFR 878.4494.

Following the effective date of the final classification rule, manufacturers will need to address the issues covered in the special controls guidance. However, the manufacturer need only show that its device meets the

recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket review of the requirements as outlined in § 807.87 will provide reasonable assurance of the safety and effectiveness of the device. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the device they intend to market.

II. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Thus, neither an environmental assessment nor an environmental impact statement is required.

III. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive

order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. The guidance for this final rule references previously approved collections of information found in FDA regulations. These collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Tepha, Inc., on May 12, 2006.

List of Subjects in 21 CFR Part 878

Medical devices.

- Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

- 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Section 878.4494 is added to subpart E to read as follows:

§ 878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

(a) *Identification.* An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant deoxyribonucleic acid (DNA) technology. The device is intended for use in general soft tissue approximation and ligation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture

Produced by Recombinant DNA Technology.” For the availability of this guidance document see § 878.1(e).

Dated: 7/23/07

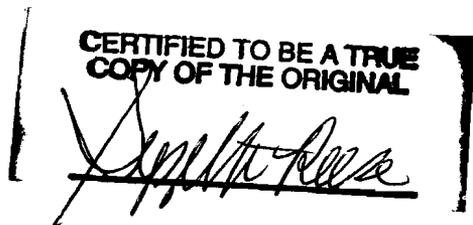
July 23, 2007.



Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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