



FEB - 8 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tepha, Inc
% Ms. Mary P. LeGraw
Director, Regulatory Affairs
840 Memorial Drive
Cambridge, Massachusetts 02139

Regulation Number: 21 CFR 878.4494
Classification: Class II
Product Code: NWJ

Re: K052225 Evaluation of Automatic Class III Designation
TephaFLEX Absorbable Suture

Dear Ms. LeGraw:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the TephaFLEX Absorbable Suture that is intended for use in general soft tissue approximation and ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the TephaFLEX Absorbable Suture, and substantially equivalent devices of this generic type into class II under the generic name, Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.

FDA identifies this generic type of device as:

An absorbable poly(hydroxybutyrate) surgical suture is 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to 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 and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device type under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device type. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On May 12, 2006, FDA filed your petition requesting classification of the TephafLEX Absorbable Suture into class II. The petition was submitted under 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 automatically classifying the TephafLEX Absorbable Suture in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the TephafLEX Absorbable Suture into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition FDA has determined that the TephafLEX Absorbable Suture intended for use in general soft tissue approximation and ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the act, the TephafLEX Absorbable Suture is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology," to address the specific risks to health associated with an absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology. The risks identified in the Special Controls Guidance Document: Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology are: improper selection and use, suture breakage, adverse tissue reaction (i.e., irritation, inflammation, immune response), and infection.

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. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology they intend to market and receive clearance, prior to marketing their device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Ms. Nada O. Hanafi at (240) 276-3555.

Sincerely yours,



Miriam Provost, Ph.D.
Deputy Director
Engineering & Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health