



Food and Drug Administration
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December 18, 2014

VasoPrep Surgical
c/o Robert Chin, Ph.D.
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Re: DEN130004
VasoPrep Surgical Marking Pen
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4670
Regulation Name: Internal Tissue Marker
Regulatory Classification: Class II
Product Code: PDW
Dated: May 3, 2013
Received: May 6, 2013

Dear Dr. Chin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the VasoPrep Surgical Marking Pen, a prescription device under 21 CFR Part 801.109 that is indicated for “use prior to or during the harvesting and preparation of vein grafts used in bypass surgery. The pen is used to demarcate selected sites and orientation of the graft”. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the VasoPrep Surgical Marking Pen, and substantially equivalent devices of this generic type, into class II under the generic name, Internal Tissue Marker.

FDA identifies this generic type of device as:

Internal Tissue Marker. An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a “not substantially equivalent” (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under

section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. 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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 22, 2013 automatically classifying the VasoPrep Surgical Marking Pen 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, nor which was subsequently reclassified into class I or class II. On May 6, 2013, FDA received your *de novo* requesting classification of the VasoPrep Surgical Marking Pen into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the VasoPrep Surgical Marking Pen 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 for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the VasoPrep Surgical Marking Pen indicated for “use prior to or during the harvesting and preparation of vein grafts used in bypass surgery. The pen is used to demarcate selected sites and orientation of the graft” can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1- Identified Risks to Health and Mitigation Measures

| Identified Risk | Mitigation Measure |
|-------------------------|--|
| Adverse tissue reaction | Biocompatibility Testing Sterilization Testing Shelf Life/Stability Testing Performance Testing Labeling |
| Ineffective Marking | Performance Testing Shelf Life/Stability Testing Labeling |
| Improper use | Labeling |

In combination with the general controls of the FD&C Act, the Internal Tissue Marker is subject to the following special controls:

1. The device must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.
2. Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.
3. Performance data must demonstrate the sterility of the device.

4. Performance data must support the shelf life of the device by demonstrating sterility, package integrity, device functionality, and material stability over the requested shelf life.
5. Labeling must include:
 - a. A warning that the device must not be used on a non-sterile surface prior to use internally.
 - b. An expiration date / shelf life.
 - c. Single use only labeling must be labeled directly on the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Internal Tissue Marker they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

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 your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact David Talley at 301-796-4861.

Sincerely yours,

Jonette R. Foy -S

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