



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Ms. Pamela Snyder
Director of Clinical and Regulatory Affairs
Spineology, Inc.
1815 Northwestern Avenue
Stillwater, Minnesota 55082-6500

Re: K014200
Device: OptiMesh™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: EZX
Dated: July 30, 2003
Received: August 1, 2003

Dear Ms. Snyder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Contraindications section of your device's labeling:

Do not use this device in patients with instability (e.g. resected or collapsed vertebral bodies or fracture of the anterior column). This device does not provide structural support.

In addition, the following warning must appear in a black box immediately below your indications for use statement of the device's labeling:

The safety and effectiveness of this device used for fusion of the interbody space has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Daniel Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014200

Device Name: OptiMesh™

FDA's Statement of the Indications For Use for device:

OptiMesh is intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g. tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates.

Spineology Inc.

Premarket Notification: OptiMesh K014200

510(k) Summary

Submitter Information

Manufacturer's Name & Address

Spineology Inc.
1815 Northwestern Avenue
Stillwater, MN 55082

Manufacturer's Contact Person

Pamela Snyder
Director of Clinical & Regulatory
Phone: 651-351-1011
Fax: 651-351-0712

Device Names

Proprietary Name: OptiMesh
Classification Name: 888.3060, appliance, fixation, spinal device;
878.3300 surgical mesh
Device Product Code: KWQ, EZX

Predicate Devices

The subject device is substantially equivalent to the predicate device, MacroPore OS Spinal System, K010911, and related predicate device, MERSILENE Mesh, a pre-amendment device.

Device Description

OptiMesh is a sterile, three-dimensional surgical mesh container made of knitted polyester yarn and offered in a range of sizes. The device is packaged in double Tyvek/Mylar pouches and a cardboard carton, and terminally sterilized.

Intended Use

OptiMesh is intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g. tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates.

The safety and effectiveness of this device used for fusion of the interbody space has not been established.

Technological Characteristic Comparisons

The device was shown to be substantially equivalent to the intended use, materials and configuration of the predicate products. Where technological differences exist, performance data was provided to demonstrate that the questions raised no new concerns about safety or effectiveness.