K033953

JUL - 6 2004

510(k) Summary (as required by 21 CFR 807.92c)

Submitter Information	**Manufacturer's Contact Person**
Spineology Inc. 1815 Northwestern Ave. Stillwater MN 55082 Establishment registration number: 2135156	Pamela R. Snyder Director of Clinical and Regulatory Affairs Phone: 651-351-1011 Fax: 651-351-0712 e-mail: psnyder@spineology.com

Device Names

Proprietary Name	OptiMesh 500E Cement Restrictor
Common/Usual Name	Cement restrictor
Classification Name	Prosthesis, Hip, Cement Restrictor
Regulatory Classification	Class II, 878.3300 Surgical Mesh
Device Product Code	JDK

Predicate Devices

The subject device is substantially equivalent to similar previously cleared predicate devices, RABEA Cement Restrictor, K020836, ImproVise Absorbable Cement Flow Restrictor, K011943 and OptiMesh, K014200.

Device Description

OptiMesh 500E is an implantable PET device indicated for use as a cement restrictor in the femur and tibia. OptiMesh 500E is manufactured from polyethylene terephthalate (PET). The device is provided pre-loaded, for ease of handling, on a disposable holder made of stainless steel. The device is available in a variety of different sizes to suit the individual pathology and anatomical conditions of the patient.

Intended Use

OptiMesh 500E is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal or tibial plateau in hip stem and total knee replacement.

WARNING: This device is not intended for use in spinal applications.
The safety and effectiveness of this device when implanted in the spine have not been established.

Technological Characteristic Comparison

The OptiMesh 500E cement restrictor is identical in materials and similar in configuration and principles of use to other devices used to contain orthopedic reconstruction materials, including bone cement and bone graft. The OptiMesh 500E intended use is equivalent to the intended use for other bone cement restrictors. The OptiMesh 500E material is identical to the previously cleared OptiMesh device material. Configurational differences between OptiMesh 500E and the predicate bone cement restrictors were addressed through testing. No new questions of safety or effectiveness for a bone cement restrictor were raised during the testing and evaluation of OptiMesh 500E. OptiMesh 500E is, therefore, substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K033953
Optimesh 500E Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: April 16, 2004
Received: April 19, 2004

Dear Ms. Snyder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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) that do not require approval of a premarket approval (PMA) application. 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 Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033953

ATTACHMENT 1: INTENDED USE STATEMENT

510(k) Number (if known):

Device Name: OptiMesh 500E Cement Restrictor

OptiMesh 500E is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal or tibial plateau in hip stem and total knee replacement.

OptiMesh 500E is not intended for use in spinal indications.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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