SEP 2 2 2003

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121
Official Contact:	Kenneth K. Kleinhenz Director of Regulatory Affairs Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Surgical Mesh
Trade/Proprietary Name:	MacroPore Surgi-Wrap MAST Bioresorbable Sheet

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 878.3300, Surgical Mesh are polymeric screens intended to be implanted to reinforce soft tissues. These devices are classified as Class II. Surgical Mesh have been assigned Product Code FTL.

INTENDED USE

The MacroPore Surgi-Wrap MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.

DEVICE DESCRIPTION

Design Characteristics

MacroPore Surgi-Wrap MAST Bioresorbable Sheet is a resorbable implant in sheet form manufactured from poly lactic acid (PLA). MacroPore Surgi-Wrap MAST Bioresorbable Sheet can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore Surgi-Wrap MAST Bioresorbable Sheet to the desired shape or size. MacroPore Surgi-Wrap MAST Bioresorbable Sheet Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which can also serve to fixate the MacroPore Surgi-Wrap MAST Bioresorbable Sheet and prevent dislocation. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet may be used in conjunction with various MacroPore manual instruments.

MacroPore Surgi-Wrap MAST Bioresorbable Sheet is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular surgical procedures. MacroPore Surgi-Wrap MAST Bioresorbable Sheet is provided in sheets of 25mm x 25mm to 500mm x 500mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MacroPore Surgi-Wrap MAST Bioresorbable Sheet ranges from 0.02 mm to 1.0 mm according to the region to be treated. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet is provided in solid sheets. The borders of the sheets may be aligned with holes to attach suture material.

Material Composition

The MacroPore Surgi-Wrap MAST Bioresorbable Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing

The MacroPore Surgi-Wrap MAST Bioresorbable Sheet is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures. Therefore, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. The relatively brief exposure anticipated during the surgical preparation of MacroPore Surgi-Wrap MAST Bioresorbable Sheet is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MacroPore Surgi-Wrap MAST Bioresorbable Sheet. Testing demonstrated that the MacroPore Surgi-Wrap MAST Bioresorbable Sheet is strong enough for the indications for use.

Mechanical testing was performed on the MacroPore Surgi-Wrap MAST Bioresorbable Sheet which determined the MacroPore Surgi-Wrap MAST Bioresorbable Sheet to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

In Vivo Testing
Animal studies were conducted to demonstrate safety and efficacy of the MacroPore Surgi-Wrap MAST Bioresorbable Sheet material. The animal studies demonstrated that the MacroPore Surgi-Wrap MAST Bioresorbable Sheet materials are safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore Surgi-Wrap MAST Bioresorbable Sheet shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore Surgi-Wrap (TS) and the Sofradim Parietex Composite Mesh; Class II medical devices that were cleared for marketing in the United States under K012025, and K002699 respectively.

Indications For Use
The MacroPore Surgi-Wrap MAST Bioresorbable Sheet shares identical indications for use principles with the predicate devices as both the MacroPore Surgi-Wrap MAST Bioresorbable Sheet and the predicate devices are indicated for the same surgical procedures.

Design and Materials
The physical designs of MacroPore Surgi-Wrap MAST Bioresorbable Sheet and the predicate devices (MacroPore Surgi-Wrap (TS) and the Sofradim Parietex Composite Mesh) are substantially equivalent, consisting of thin semi-rigid sheets that are fabricated from resorbable materials. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet and the MacroPore Surgi-Wrap (TS) predicate device are fabricated from the identical raw material while the Sofradim Parietex predicate is fabricated from resorbable collagen. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet and the predicates also share design features of allowing for contouring. The MacroPore Surgi-Wrap MAST Bioresorbable Sheet and the MacroPore Surgi-Wrap (TS) predicate are fully contourable when heated to approximately 55°C. The thickness of the predicate devices and the MacroPore Surgi-Wrap MAST Bioresorbable Sheet are substantially equivalent as the thinnest MacroPore Surgi-Wrap MAST Bioresorbable Sheet thickness is identical to the Surgi-Wrap (TS) predicate (0.02mm) and virtually identical to the thin film layer on the Sofradim Parietex Composite Mesh (0.04mm). The dimensions of the predicate devices are also comparable to the MacroPore Surgi-Wrap MAST Bioresorbable Sheet as both devices are provided in circular and rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore Surgi-Wrap MAST Bioresorbable Sheet are substantially equivalent to the predicate devices with respect to mechanical strength. In addition to physical characteristics, both the predicate device and the MacroPore Surgi-Wrap MAST Bioresorbable Sheet can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2003

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, California 92121

Re: K031955
Trade/Device Name: MacroPore Surgi-Wrap MAST Bioresorbable Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 20, 2003
Received: June 25, 2003

Dear Mr. Kleinhenz:

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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

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.

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

If you desire specific advice for your device on our labeling regulation (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" (21CFR 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031955

Device Name: **MacroPore Surgi-Wrap MAST Bioresorbable Sheet**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

Miriam C. Provost

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

510(k) Number K031955