

(P.10A3)

DEC 03 2001

K012025 SUMMARY

MacroPore Surgi-Wrap (TS)

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ADMINISTRATIVE INFORMATION

Manufacturer Name: MacroPore, 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 (TS)

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 FTM.

INTENDED USE

The MacroPore Surgi-Wrap (TS) 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. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

DEVICE DESCRIPTION

Design Characteristics

MacroPore Surgi-Wrap (TS) is a resorbable implant in sheet form manufactured from poly lactic acid (PLA). MacroPore Surgi-Wrap (TS) 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 (TS) to the desired shape or size. MacroPore Surgi-Wrap (TS) 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 (TS) can be rolled into a tube or used as a flat sheet. It can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which also can serve to fixate the MacroPore Surgi-Wrap (TS) and prevent dislocation. The MacroPore Surgi-Wrap (TS) may be used in conjunction with various MacroPore manual instruments.

MacroPore Surgi-Wrap (TS) is provided in sheets of 10mm x 10mm to 120mm x 120mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MacroPore Surgi-Wrap (TS) ranges from 0.02 mm to 2.0 mm according to the region to be treated. The MacroPore Surgi-Wrap (TS) is provided with and without macroporous holes. The macroporous holes range in size from 50 microns to 3,000 microns in diameter and may be in aligned, offset, or random patterns. The borders of the sheets may be aligned with holes to attach suture material.

Material Composition

The MacroPore Surgi-Wrap (TS) is fabricated from polylactic acid (PLA).

In Vitro Testing

Because the MacroPore Surgi-Wrap (TS) is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, 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. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore Surgi-Wrap (TS) is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MacroPore Surgi-Wrap (TS). Testing demonstrated that the MacroPore Surgi-Wrap (TS) is strong enough for the indications for use.

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

In Vivo Testing

An animal study was conducted to demonstrate safety and efficacy of the MacroPore Surgi-Wrap (TS) material. The animal studies demonstrated that the MacroPore Surgi-Wrap (TS) materials are appropriate for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore Surgi-Wrap (TS) shares indications and design principles with the following predicate devices, which have been determined by FDA to be substantially equivalent to the following pre-amendment devices: SupraFOIL, Dexon, Biosling, Vicryl Mesh, and Vipro Mesh.

Indications For Use

The MacroPore Surgi-Wrap (TS) shares identical indications for use principles with the predicate devices as both the MacroPore Surgi-Wrap (TS) and the predicate devices are indicated for the same surgical procedures.

Design and Materials

The physical designs of MacroPore Surgi-Wrap (TS) and the predicate devices (SupraFOIL, Dexon, Biosling, Vicryl Mesh, and Vipro Mesh) are substantially equivalent, consisting of a thin semi-rigid sheet that allows for contouring. Both the predicate device and the MacroPore Surgi-Wrap (TS) have a semi-rigid construction. The MacroPore Surgi-Wrap (TS) and the predicates also share design features of allowing for contouring. The MacroPore Surgi-Wrap (TS) is fully contourable when heated to approximately 55°C. The thickness of the predicate devices and the MacroPore Surgi-Wrap (TS) are substantially equivalent as the MacroPore Surgi-Wrap (TS) thickness ranges are essentially a subset of the predicate ranges. The MacroPore Surgi-Wrap (TS) has a thickness range of 0.02mm - 2.0mm which is substantially equivalent to the predicate device that ranges in thickness from 0.05mm - 2.0mm. The dimensions of the predicate device are also comparable to the MacroPore Surgi-Wrap (TS) as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore Surgi-Wrap (TS) are also substantially equivalent to the predicate devices. In addition to physical characteristics, both the predicate device and the MacroPore Surgi-Wrap (TS) 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

DEC 03 2001

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
Macropore, Inc.
6740 Top Gun St.
San Diego, California 92121

Re: K012025
Trade Name: Macropore Surgi-Wrap (TS)
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: September 28, 2001
Received: October 1, 2001

Dear Mr. Kleinhenz:

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 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.

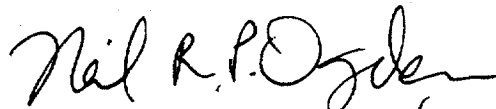
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Kenneth Kleinhenz

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 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,



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

Enclosure

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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 Susan Walker OR

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

Over-The-Counter Use

510(k) Number K012025