

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
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DEVICE NAME

Classification Name: Plate, Bone

Trade/Proprietary Name: MacroPoreOS Protective Sheet

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3030 Bone Fixation Appliances are intended for use in orthopedic procedures and are classified as Class II. Bone Plates have been assigned Product Code HRS.

INTENDED USE

The MacroPoreOS Protective Sheet is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPoreOS Protective sheet is also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, the MacroPoreOS Protective Sheet is intended to maintain the relative position weak bony tissue in trauma and reconstructive orthopedic procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the MacroPoreOS Protective Sheet is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:

- Tumor resections where bone strength has not been compromised
- Iliac crest harvests

This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

DEVICE DESCRIPTION

Design Characteristics

MacroPoreOS Protective Sheet is a resorbable, macroporous implant in sheet form manufactured from polylactic acid (PLA). MacroPoreOS Protective 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 MacroPoreOS Protective Sheet to the desired shape or size. MacroPoreOS Protective Sheet is fully malleable when heated to approximately 65°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The MacroPoreOS Protective Sheet can be rolled into a tube or used as a flat sheet. MacroPoreOS Protective Sheet can be used either alone or in conjunction with internal bone fixation devices such as plates and screws, which also can serve to further stabilize the anatomical region. The MacroPoreOS System includes MacroPoreOS Protective Sheets, a selection of resorbable MacroSorb Screws, MacroSorb Tacks and associated manual instruments.

MacroPoreOS Protective Sheet is provided in sheets of 20 x 20 mm to 120 x 120 mm and will be provided in other sizes as needed for particular surgical procedures. The pore size ranges from 500 microns to 2500 microns in diameter, with pores distributed uniformly throughout the sheet in an offset or aligned pattern. The thickness of the MacroPoreOS Protective Sheet ranges from 0.50 mm to 2.0 mm according to the orthopedic region to be treated, however, not to exceed a total mass of 18 grams.

Material Composition

The MacroPoreOS Protective Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing

Because the MacroPoreOS Protective 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, 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 MacroPoreOS Protective Sheet is not expected to have a significant effect on its mechanical properties.

Accelerated aging testing was performed on MacroPoreOS Protective Sheet. Testing demonstrated that the MacroPoreOS Protective Sheet is as rigid and as strong as the predicate after a simulated 6 month *in vivo* exposure. Furthermore, simulated *in vivo* accelerated testing indicates that the MacroPoreOS Protective Sheet retains all of its strength for the first 9 months and a steadily decrease in strength to zero after approximately 18 months.

Mechanical testing was performed on the MacroPoreOS Protective Sheet which determined the MacroPoreOS Protective Sheet to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Crystallinity was tested for by DSC (differential scanning calorimetry). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches its melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes. From this we verify the implants are amorphous or non-crystalline.

EQUIVALENCE TO MARKETED PRODUCT

MacroSorbOS Protective Sheet shares indications and design principles with the following predicate device, which has been determined by FDA to be substantially equivalent to the following pre-amendment devices: Sofamar Danek Timesh (K974017).

Indications For Use

The MacroPoreOS Protective Sheet shares indications for use with the predicate device as both the MacroPoreOS Protective Sheet and the Timesh predicate are indicated for reinforcing weak bony tissue in orthopedic procedures. The MacroPoreOS Protective Sheet and the Timesh predicate also share cement restriction indication for use.

Design and Materials

The physical designs of MacroSorbOS Protective Sheet and the predicate device (Sofamar Danek Timesh) are similar, consisting of a thin semi-rigid sheet with macroporosity. Both the predicate device and the MacroSorbOS Protective Sheet have a semi-rigid construction with pores of similar diameter and spacing. The pore size and spacing of the predicate device is within the pore size and spacing specifications of the MacroSorbOS Protective Sheet. The dimensions of the predicate device are also comparable to the MacroSorbOS Protective sheet as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroSorbOS Protective Sheet are substantially equivalent to the predicate device with respect to initial and *in vivo* strengths and rigidity. In addition to physical characteristics, both the predicate device and the MacroSorbOS Protective Sheet can be cut to specific shapes and sizes by the end user. The titanium device differs from MacroSorbOS Protective Sheet device in that it may be left in place permanently or must be removed surgically, whereas the polymer devices are intended to be metabolized by the body and do not require removal.

SUMMARY : TABLE OF SUBSTANTIAL EQUIVALENCE

Intended Use	Subject Device	Predicate Device	Related Device	Related Device
<p>The MacroSorbOS Protective Sheet is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPoreOS Protective sheet is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the MacroPoreOS Protective Sheet is intended to maintain the relative position weak bony tissue in trauma and reconstructive orthopedic procedures involving: Long bones, Flat bones, Short bones, Irregular bones, Appendicular skeleton, Thorax. When used alone (without traditional rigid fixation), the MacroPoreOS Protective Sheet is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving: Tumor resections where bone strength has not been compromised, Iliac crest harvests. This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.</p>	<p>MacroSorbOS Protective Sheet</p> <p>Timesh (K974017) Sofamar Danek</p> <p>For use in any oral-maxillo-cranio-facial surgical reconstructive procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the Timesh system is also indicated for use in reinforcing weak bony tissues in orthopaedic surgical procedures such as pelvic reconstructions, acetabular reconstruction, and cement restriction. This product is not intended for spinal use.</p>	<p>MacroPore Protective Sheet (Protego System) (K972913)</p> <p>MacroPore Protective Sheet is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton:</p> <ol style="list-style-type: none"> 1. Comminuted fractures of the naso-ethmoidal and infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Trauma of the midface or craniofacial skeleton 4. Reconstructive procedures of the midface or craniofacial skeleton. <p>The system is not intended for use in the mandible and/or for full load bearing procedures.</p>	<p>MacroPore Protective Sheet (K983360)</p> <p>MacroPore Protective Sheet is intended to facilitate healing in trauma, reconstruction and bone augmentation procedures of the mandible. The following specific indications are included: to maintain the relative position of bony fragments in trauma and bone graft porcedures, and to contain and prevent migration and shifting of autograft, allograft and/or bone graft substitutes that may be necessary in reconstructive procedures.</p>	<p>Sheets of 0.50 – 2.0 mm thickness, sizes 20 x 20 mm to 120 x 120 mm or as required.</p> <p>Plates, screws and tacks of various sizes.</p> <p>Poly (L-lactide-co-D,L-lactide) 70:30, amorphous</p> <p>HRS and HWC</p>
<p>Design</p>	<p>Sheets of 0.50 – 2.0 mm thickness, sizes 20 x 20 mm to 120 x 120 mm or as required.</p>	<p>Sheets of 0.2mm thickness, size 76 x 45 mm.</p>	<p>Plates, screws and tacks of various sizes.</p>	<p>Sheets of 0.50 – 2.0 mm thickness, sizes 20 x 20 mm to 120 x 120 mm or as required.</p>
<p>Material</p>	<p>Poly (L-lactide-co-D,L-lactide) 70:30, amorphous</p>	<p>Titanium</p>	<p>Poly (L-lactide-co-D,L-lactide) 70:30, amorphous</p>	<p>Poly (L-lactide-co-D,L-lactide) 70:30, amorphous</p>
<p>Product Code</p>	<p>HRS</p>	<p>HRS</p>	<p>HRS and HWC</p>	<p>JEY</p>



JUL 24 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994158
Trade Name: MacroSorbOS Protective Sheet
Regulatory Class: II
Product Codes: HRS, MAI, HWC
Dated: April 24, 2000
Received: April 25, 2000

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: MacroPoreOS Protective 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

Denise R. Vochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994158