ADMINISTRATIVE INFORMATION

SEP 21 2006

Manufacturer Name:

MAST Biosurgery, Inc.
6749 Top Gun Street, Suite C
San Diego, CA 92121

Official Contact:

Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Surgical Mesh, Polymeric

Trade/Proprietary Name: Surgi-Wrap MAST Bioresorbable Sheet

ESTABLISHMENT REGISTRATION NUMBER

3004661493

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 and FTM.

INTENDED USE

The Surgi-Wrap MAST Bioresorbable Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the tissues.

The device is indicated for open and laparoscopic / endoscopic procedures. Laparoscopic / endoscopic procedures are limited to sizes from 0.02mm – 0.2mm in thickness.

DEVICE DESCRIPTION

Design Characteristics

The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is a resorbable implant in sheet form manufactured from polylactic acid (PLA). The Surgi-Wrap MAST Bioresorbable Sheet can be cut with scissors to the desired shape and size. The Surgi-Wrap MAST Bioresorbable 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 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 Surgi-Wrap MAST Bioresorbable Sheet and prevent dislocation. The Surgi-Wrap MAST Bioresorbable Sheet may be used in conjunction with various MAST Biosurgery Class I manual instruments (forceps, scissors, clamps, etc.).

The MAST Biosurgery 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. The MAST Biosurgery 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 MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet ranges from 0.02 mm to 1.0 mm according to the region to be treated. The MAST Biosurgery 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 MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing

The MAST Biosurgery 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 MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is not expected to have a significant effect on its mechanical properties.

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

Mechanical testing was performed on the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet which determined the MAST Biosurgery 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 MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet material. The animal studies demonstrated that the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet materials are safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

The MAST Biosurgery SurgiWrap 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: Integra LifeSciences Tendon Wrap (K053655) and MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332); Class II medical devices that were cleared for marketing in the United States under K053655 and K050332 respectively.

Indications For Use
The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet shares indications for use principles with the predicate devices as all devices are indicated for use in the same general surgery procedures. Furthermore, the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet shares identical indications for use language with each of the predicate devices.

Design and Materials
The physical designs of MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the Integra LifeSciences Tendon Wrap (K053655) and the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332) predicate devices are substantially equivalent as they are all fabricated from a bioresorbable material with physical properties of being flexible and semi-rigid. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and all predicates share fundamental design features of allowing for contouring as the semi-rigid polymeric design principles shared by the subject device and all predicates demonstrate substantial equivalence with respect to intraoperative contouring. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is substantially equivalent to the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332) predicates as they are all thin, semi-rigid sheets provided in sizes ranging from 25mm x 25mm and 500mm x 500mm with various thicknesses ranging from 0.02mm to 1.0mm. The mechanical characteristics of the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet are substantially equivalent to the predicate devices. In addition to physical characteristics, both the predicate device and the MAST Biosurgery 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 21 2006

Mast Biosurgery, Inc.
% Mr. Kenneth K. Kleinhenz
Regulatory Affairs
6749 Top Gun Street, Suite C
San Diego, California 92121

Re: K061473
Trade/Device Name: Surgi-Wrap MAST Bioresorbable Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: July 29, 2006
Received: August 1, 2006

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 (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 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 continue 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K061473

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

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061473