K090637

JAN – 7 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MAST Biosurgery, Inc. 6749 Top Gun Street, Suite 108 San Diego, CA 92121
Official Contact:	Kenneth K. Kleinhenz Regulatory Affairs Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Intracardiac Patch
Trade/Proprietary Name:	Cardio-Wrap Bioresorbable Sheet

ESTABLISHMENT REGISTRATION NUMBER

3004661493

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 870.3470, an Intracardiac Patch is a fabric device intended to be placed in the heart for use to repair septal defects, for patch grafting, and to repair tissue. These devices are classified as Class II. Intracardiac Patches have been assigned Product Code DXZ.

INTENDED USE

The Cardio-Wrap Bioresorbable Sheet is intended for reconstruction and repair of defects of the pericardium

DEVICE DESCRIPTION

Design Characteristics

MAST Biosurgery Cardio-Wrap Bioresorbable Sheet is a resorbable implant in sheet form manufactured from polylactic acid (PLA). MAST Biosurgery Cardio-Wrap Bioresorbable Sheet can be cut with scissors to the desired shape and size. The MAST Biosurgery Cardio-Wrap can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which can also serve to fixate the MAST Biosurgery Cardio-Wrap and prevent dislocation.

MAST Biosurgery Cardio-Wrap 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. MAST Biosurgery Cardio-Wrap Bioresorbable Sheet is provided in sheets of 10mm x 10mm 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 Cardio-Wrap Bioresorbable Sheet ranges from 0.02 mm to 1.0 mm according to the region to be treated. The MAST Biosurgery Cardio-Wrap is provided in solid sheets. The borders of the sheets may be aligned with holes to attach suture material.

Material Composition

The MAST Biosurgery Cardio-Wrap Bioresorbable Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing

Mechanical testing was performed on the MAST Biosurgery Cardio-Wrap Bioresorbable Sheet which determined the MAST Biosurgery Cardio-Wrap Bioresorbable Sheet to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions. Aging testing was performed on MAST Biosurgery Cardio-Wrap Bioresorbable Sheet. Testing demonstrated that the MAST Biosurgery Cardio-Wrap is strong enough for the indications for use.

In Vivo Testing

Various animal studies were conducted to demonstrate safety and efficacy of the MAST Biosurgery Cardio-Wrap Bioresorbable Sheet material. The animal studies demonstrated that the MAST Biosurgery Cardio-Wrap materials are safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

MAST Biosurgery Cardio-Wrap 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 Biosurgery Cardio-Wrap (K031785), CorMatrix Cardiovascular CorMatrix Pericardial Patch (K051405), Bio-Vascular Supple Peri-Guard (K983602), W. L. Gore Preclude IMA Sleeve (K960532), W. L. Gore Preclude Vessel Guard K061727), and MacroPore Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K031955), Class II medical devices that were cleared for marketing in the United States under K031785, K051405, K983602, K960532, K061727, K031955, and respectively.

Indications For Use

The MAST Biosurgery Cardio-Wrap Bioresorbable Sheet shares identical indications for use principles with the predicate devices as the MAST Biosurgery Cardio-Wrap Bioresorbable Sheet and the predicate devices are indicated for the same surgical procedures.

Design and Materials

The design of MAST Biosurgery Cardio-Wrap Bioresorbable Sheet and the predicate devices MacroPore Biosurgery Cardio-Wrap (K031785), CorMatrix Cardiovascular CorMatrix Pericardial Patch (K051405), Bio-Vascular Supple Peri-Guard (K983602), W. L. Gore Preclude IMA Sleeve (K960532), W. L. Gore Preclude Vessel Guard K061727), MacroPore Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K031955), are substantially equivalent as they are all sterile, single use, thin, flat, rectangular sheets with design characteristics of being flexible and semi-rigid devices that can be contoured to the anatomy in situ and cut to the desired shape with surgical scissors. The MAST Biosurgery Cardio-Wrap Bioresorbable Sheet and the predicate devices MacroPore Biosurgery Cardio-Wrap (K031785), Bio-Vascular Supple Peri-Guard (K983602), W. L. Gore Preclude IMA Sleeve (K960532), W. L. Gore Preclude Vessel Guard K061727), MacroPore Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K031955), are substantially equivalent as they all share material characteristics of being fabricated from a polymer material and all devices are free from any human or animal materials. Furthermore, the MAST Biosurgery Cardio-Wrap and the predicate devices MacroPore Biosurgery Cardio-Wrap (K031785), CorMatrix Cardiovascular CorMatrix Pericardial Patch (K051405), MacroPore Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K031955) are substantially equivalent as they all share the material characteristics of being bioresorbable. The MAST Biosurgery Cardio-Wrap Bioresorbable Sheet and the predicate devices MacroPore Biosurgery Cardio-Wrap (K031785) and the MacroPore Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K031955) are substantially equivalent as they all share material and design features of being fabricated from a bioresorbable polymer, they all share substantially equivalent shapes and sizes as they are all provided in sheet that range in size from 0.02mm – 1.0mm in thickness and sizes of 10mm x 10mm up to 500mm x 500mm, and they share substantially equivalent mechanical strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mast Biosurgery USA Inc.
C/O Mr. Kenneth K. Kleinhenz
6749 Top Gun Street, Suite C
San Diego, California 92121

JAN - 7 2010

Re: K090637
Trade/Device Name: Cardio-Wrap Bioresorbable Sheet
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: DXZ
Dated: November 23, 2009
Received: November 24, 2009

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). 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 labeling:

> The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for reconstruction and repair of defects of the pericardium must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

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

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-5579. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K090637

Device Name: Cardio-Wrap Bioresorbable Sheet

Indications For Use: The Cardio-Wrap Bioresorbable Sheet is intended for reconstruction and repair of defects of the pericardium.

Prescription Use ✓ 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 Cardiovascular Devices

510(k) Number K090637