January 7, 2021

MAST Biosurgery
% Kenneth Kleinhenz
Regulatory Affairs Consultant
QSR Consulting
10807 Dakota Ranch Rd.
Santee, California 92071

Re: K200918
Trade/Device Name: SurgiWrap FROST
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: November 21, 2020
Received: November 25, 2020

Dear Kenneth 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200918

Device Name
SurgiWrap FROST Bioresorbable Protective Sheet

Indications for Use *(Describe)*

The SurgiWrap FROST Bioresorbable Protective 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. This includes, but is not limited to the following procedures: colon and rectal prolapse. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K200918 - 510(k) Summary SurgiWrap FROST Bioresorbable Protective Sheet Page 1 of 4**

**Date: 06 January 2021**

**510(k) Number: K200918**

## ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer Name: | MAST Biosurgery, Inc.<br>6749 Top Gun Street, Suite 108<br>San Diego, CA 92121 |
| Official Contact: | Kenneth K. Kleinhenz<br>Regulatory Affairs<br>Telephone (619) 244-9573<br>Fax (858) 550-8060 |

## DEVICE NAME

| | |
|---|---|
| Classification Name: | Surgical Mesh, Polymeric |
| Trade/Proprietary Name: | SurgiWrap FROST<br>Bioresorbable Protective 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.

## INTENDED USE

The SurgiWrap FROST Bioresorbable Protective 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. This includes, but is not limited to the following procedures: colon and rectal prolapse. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures.

## DEVICE DESCRIPTION

### Design Characteristics

The SurgiWrap FROST Bioresorbable Protective Sheet is a biodegradable surgical mesh for trauma and reconstructive surgical procedures involving soft tissues. The SurgiWrap FROST Bioresorbable Protective Sheet is available in various sizes (50mm x 65mm to 200mm x 130mm with a thickness of 0.02mm to 0.04mm) for use in maintaining the relative position of healing tissues. The device is a solid, semi-transparent thin film sheet that is placed directly on the anatomy. The device has two surfaces, one surface is smooth and the opposite side of the device has a micro-texture. The textured surface of the device allows for controlled gripping with wet gloves. The textured surface of the device readily clings and conforms to surgical tissues. The textured surface also facilitates device placement by minimizing slippage of the device during handling as well as resisting movement of the device during the installation process. The SurgiWrap FROST Bioresorbable Protective Sheet can be cut with scissors to the desired shape and size according to the needs of the physician. The SurgiWrap FROST Bioresorbable Protective 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 SurgiWrap FROST Bioresorbable Protective Sheet and prevent dislocation. The implants maintain the stability of soft tissues during the healing period and are to avoid a second surgical procedure that may otherwise be necessary to remove permanent implants. The implants are not intended for use where permanent implants are required.

### Material Composition

The MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet is fabricated from polylactic acid (PLA).

## NON-CLINICAL TESTING

Performance testing was conducted on MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet. Testing demonstrated that the MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet is strong enough for its intended use.

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

Biocompatibility studies were conducted per ISO 10993-6 to demonstrate safety and efficacy of the MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet material. The biocompatibility studies demonstrated that the MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet materials are safe for its intended use.

## EQUIVALENCE TO MARKETED PRODUCT

The MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet shares indications and design principles with the following predicate devices: MAST Biosurgery SurgiWrap MAST Bioresorbable Protective Sheet predicate device (K050332) and the Biomet Mesofol Reference device (K062558); Class II medical devices that were cleared for marketing in the United States under K050332 and K062558 respectively.

**Indications For Use**

The SurgiWrap FROST Bioresorbable Protective Sheet, the MAST Biosurgery SurgiWrap MAST Bioresorbable Protective Sheet predicate device (K050332), and the Biomet Mesofol (K062558) Reference device are substantially equivalent with respect to their indications for use as they are all indicated for the same intended use of soft tissue support in various abdominal anatomy.

**Design and Materials**

The design principles of the MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet and the MAST Biosurgery SurgiWrap MAST Bioresorbable Protective Sheet predicate devices (K050332) and Reference device [Biomet Mesofol (K062558)] are substantially equivalent, consisting of sterile, single-use devices that are flexible and malleable implants fabricated from a thin sheet resorbable polymeric material and are provided in various sizes that they can be cut to shape intra-operatively and subsequently placed on, under or and around pelvic and abdominal anatomy. All devices also share the common design principles of being 100% composed of the same resorbable polymeric material that is used to reinforce soft tissues. All devices share substantially equivalent thickness, shapes, and sizes. The devices also share substantially equivalent mechanical strength.

The SurgiWrap FROST Bioresorbable Protective Sheet is substantially equivalent to the predicate and Reference devices in the following respects:

| | **Subject Device** | **Predicate Device** | **Reference Device** |
|---|---|---|---|
| | **MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet** | **MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332)** | **Biomet Mesofol (K062558)** |
| **Intended Use** | The SurgiWrap FROST Bioresorbable Protective 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. This includes, but is not limited to the following procedures: colon and rectal prolapse. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. | The SurgiWrap 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. This includes, but is not limited to the following procedures: colon and rectal prolapse. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02mm - 0.2mm in thickness. | Mesofol® Surgical Sheet is indicated when temporary wound support is required to reinforce soft tissues where weakness exists, or in conjunction with hernia repair or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The resorbable protective sheet minimizes tissue attachment to the device in case of direct contact with the viscera. |

**K200918 - 510(k) Summary SurgiWrap FROST Bioresorbable Protective Sheet Page 4 of 4**

| | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | **MAST Biosurgery SurgiWrap FROST Bioresorbable Protective Sheet** | **MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332)** | **Biomet Mesofol (K062558)** |
| **Design** | Sheets ranging in size from 65mm x 50mm to 200mm x 130mm with thickness of 0.02mm – 0.04mm | Sheets ranging in size from 25mm x 25mm to 500mm x 500mm with thickness of 0.02mm – 1.0mm | Sheets ranging in size from 40mm x 40mm to 200mm x 250mm with thickness of 0.04mm |
| **Material** | Polylactic acid | Polylactic acid | Polylactic acid and Caprolactone |
| **Resorbable Material** | Yes | Yes | Yes |
| **Sheet Thickness** | 0.02 – 0.04mm | 0.02 – 1.0mm | 0.04mm |
| **Sterilization** | eBeam Irradiation | eBeam Irradiation | eBeam Irradiation |
| **Embossed with a Micropattern** | Yes | No | No |
| **Product Code** | FTL | FTL | FTL |
| **CFR Section** | 878.3300 | 878.3300 | 878.3300 |