

510(k) Summary

JUN 20 2007

Preparation Date: March 15, 2006

Applicant/Sponsor: Biomet Orthopedics Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

Contact Person: Erika Martin

Proprietary Name: Mesofol[®] Surgical Sheet

Common Name: Mesh, Surgical, Polymeric

Classification Name: FTL, 878.3300

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Mesofol[®] Surgical Sheet is substantially equivalent to MacroPore Surgi-Wrap MAST Bioresorbable Sheet K031955 and Polyganics VivoSorb[®] Sheet K042811.

Device Description: Mesofol[®] Surgical Sheet is an implantable, resorbable, polymeric surgical sheet manufactured by ITV Denckendorf in Germany. Mesofol[®] Surgical Sheet is offered in various sizes 4cm x 4cm to 20cm x 25cm and is 40 μ m in thickness. Mesofol[®] Surgical Sheet can be cut into different sizes and shapes by the end user. The sheet can be fixed with degradable suture material in situations where the anatomical conditions of the wound area are not suited to adequately fix the sheet.

Mesofol[®] Surgical Sheet is manufactured from a lactide-caprolactone copolymer. Mesofol[®] Surgical Sheet is chemically broken down by hydrolytic cleavage of the polymer, giving rise to three monomers: 6-hydroxycaproic acid, D-lactic acid, and L-lactic acid. 6-Hydroxycaproic acid is broken down to acetyl-CoA units via β -oxidation (fatty acid metabolism) for further degradation via the Krebs cycle. L-Lactate is broken down in the Cori cycle (lactic acid cycle) to glucose via pyruvate. These two monomers are thus degraded to products that are physiologically metabolized by the body.

In vitro studies have shown that Mesofol[®] Surgical Sheet is impermeable to microorganisms and large molecules until it starts to biodegrade. Degradation is likely to involve adhesion molecule and fibrin attachment to both sides of the sheet.

Preclinical *in vitro* and *in vivo* studies have shown that Mesofol[®] Surgical Sheet takes approximately 4 to 6 weeks to biodegrade.

Intended Use: 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.

Summary of Technologies: Similar to the predicate devices, Mesofol[®] Surgical Sheet is substantially equivalent to other surgical films or meshes with respect to its design as a thin, flexible, polymeric sheet that is used where temporary wound support is required to reinforce soft tissues or for the addition of a reinforcing bridging material to obtain the desired surgical result. Biocompatibility testing was performed and demonstrated that Mesofol[®] Surgical Sheet is biocompatible as a surgical sheet.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet, Inc.
% Ms. Erika Martin
Manager, Human Tissue and Applied
Technology Regulation
P.O. Box 587
Warsaw, Indiana 46581-0587

JUN 20 2007

Re: K062558
Trade/Device Name: Mesofol[®] Surgical Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: May 10, 2007
Received: May 16, 2007

Dear Ms. Martin:

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. 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.

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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), 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/industry/support/index.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 (if known): K062558

Device Name: Mesosfol[®] Surgical Sheet

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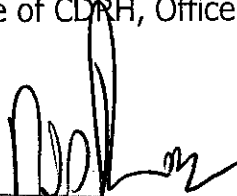
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

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

Concurrence of CDH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K062558

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