

NOV - 8 2004

**510(k)**  
**Summary of Safety and Effectiveness**

**Submitter:** Polyganics BV  
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The Netherlands  
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**Date Prepared:** Oct 7, 2004

**General Provisions:** Trade Name: VivoSorb Sheet  
Common Name: Absorbable Polymeric Surgical Mesh  
Classification Name: Surgical Mesh, Polymeric, 21 CFR 878.3300  
Device Classification: Class II

**Predicate Devices:**

• Surgi Wrap MAST	MacroPore, Inc	K031955
• IMMIX™	Obi OsteoBiologics	K032673

**Performance Standards** For the VivoSorb Sheet performance, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.

**Indications for Use** The VivoSorb Sheet is indicated for the use as a temporary wound support, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.

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**Device Description** The VivoSorb Sheet is designed to be a flexible and transparent resorbable poly (DL-lactide-co-ε-caprolactone) sheet to provide support to soft tissue where weakness exists.

The VivoSorb Sheet is provided sterile in Tyvek pouch packages in a variety of sizes.

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**Performance Data:** The safety and effectiveness of the VivoSorb Sheet have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- Aging testing
- Mechanical testing

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**Summary of Substantial Equivalence** The design, fundamental technology and intended use (safety and efficacy) featured with the VivoSorb Sheet are substantially equivalent to those featured with the competitor devices Surgi Wrap (ref. 510(k) 031995; MarcoPore, Inc) and the Immix™ (ref. 510(k) 032673, Obi OsteoBiologics, Inc).

Biocompatibility, mechanical and physical property testing and in vitro degradation testing provide reasonable scientific evidence that VivoSorb Sheet is substantially equivalent to the predicate devices. Evaluation of the Polyganics VivoSorb Sheet based on biocompatibility testing, animal tests, results from literature and the comparison of the VivoSorb Sheet with its predicate devices, shows that the VivoSorb Sheet is safe for implantation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Jan Nieuwenhuis  
Managing Director  
Polyganics BV  
L.J. Zielstraweg 1  
9713 GX Groningen  
The Netherlands

Re: K042811  
Trade/Device Name: VivoSorb<sup>®</sup> Sheet  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: October 8, 2004  
Received: October 14, 2004

Dear Ms. Nieuwenhuis:

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.

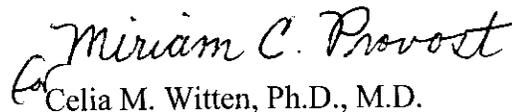
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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" (21 CFR 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 (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

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**Indications for Use Form**

510(k) Number: K042811

Device Name: **VivoSorb® Sheet**

Indications for Use:

The VivoSorb Sheet is indicated for the use as a temporary wound support, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Miriam C. Provost*  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number**   K042811