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JUL 17 2012

Section 5 – 510(k) Summary for TiO2Mesh™

1. Submission Sponsor

Biocer Entwicklungs GmbH
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COUNTRY: Germany
Phone: 49 0 921-78-77-70-0
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Contact: Martina Feldmann Ph.D., Product Manager

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
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3. Date Prepared

17 July 2012

4. Device Name

Trade/Proprietary Name: TiO2Mesh™
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh Polymeric
Classification Regulation: 878.3300 Surgical Mesh
Classification Panel: 878 General and Plastic Surgery
Product Code:
OXJ, Mesh, Surgical, non-absorbable, large Abdominal Wall defects
FTL, Mesh, Surgical, polymeric
Device Class: 2

FDA Establishment Registration #: Not available yet.

5. Predicate Devices

GfE Medizintechnik GmbH ; TiMeshTC
Bard; SoftMesh

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6. Device Description

TiO2Mesh™ is made from a monofilament polypropylene thread and has a large-pore structure with blue orientation stripes. The surgical mesh implant has a titanium dioxide coated surface. The fabric can be stretched in both directions and is highly flexible to react to body dynamics in terms of elasticity. TiO2Mesh™ is available in different shapes and sizes (product flyer TiO2Mesh™).

7. Intended Use

TiO_2Mesh™ is a surgical mesh implant specifically indicated for repair of tissue defects of the abdominal wall, where a non-reabsorbable support material is required. Relevant applications include the repair of inguinal and incisional hernia in all common surgical methods. TiO2Mesh™ can be used for both laparoscopic and other open procedures.

8. Technological Characteristics and Substantial Equivalence

The following table compares the TiO2MeshTM to the TiMesh-TC with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Table

Manufacturer	**Biocer Entwicklungs GmbH**	**GfE Medizintechnik GmbH**	**Bard**
Trade Name	TiO2 Mesh	TiMesh-TC	Soft Mesh
510(k) Number	Not Available yet	KO31225	KO52155
Product Code	FTL	FTL	FTL
Regulation Number	878.3300	878.3300	878.3300
Regulation Name	Surgical mesh.	Surgical mesh. The TiMESH also	Surgical mesh. Bard® Large Pore
Indications for use:	TiO2Mesh™ is a surgical mesh implant specifically indicated for repair of tissue defects of the abdominal wall, where a non-reabsorbable support is required. Relevant applications include the repair	known as TiMESH-TC, along with Ethicon Inc. Prolene Soft Mesh, U.S.S.C.'s Non Absorbable Polypropylene Surgical Mesh are intended to be used for the reinforcement of tissue during surgical repair. Thus, the TiMESH also known as TiMESH-TC mesh and all the predicates	Soft Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. Bard Large Pore Soft Mesh Pre-Shaped is indicated for the repair of inguinal hernia defects

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Manufacturer	Biocer Entwicklungs GmbH	GfE Medizintechnik GmbH	Bard
Trade Name	TiO2 Mesh	TiMesh-TC	Soft Mesh
	of inguinal and incisional hernia in all common surgical methods. TiO2Mesh™ can be used for both laparoscopic and other open procedures.	have the same intended use. The TiMESH is specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical, and incisional hernias; rectal, vaginal, and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair. The TiMESH has the same indications for use as a combination of the predicated devices TIMESH is a perscriptive device and should only be used by a licensed physician	
Material	PP + Titanium	PP + Titanium	PP
Grammage	43	65	44
Pore size (mm)	2.8	1	2.5
Biocompatible	Yes	Yes	Yes
Physical Properties	Comparable FDA Guidance used	Comparable FDA Guidance used	Comparable (unknown whether FDA Guidance was used)

9. Non-Clinical Testing

a. In vitro Cytotoxicity Assay: Cell Growth Analysis via BCA-Staining with an Extract of TiO2Mesh™
b. Irritation Test (Intracutaneous Reactivity) with TiO2Mesh™
c. Test for Sensitisation (Local Lymph Node Assya – LLNA) TiO2Mesh™

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d. Acute Systemic Toxicity in the Mouse with 4 Extracts of TiO2Mesh™
e. Test for the Local Effects after Implantation (7 days period) with TiO2Mesh™
f. Test for the Local Effects after Implantation (90 days period) with TiO2Mesh™
g. Investigation of Extractable Organic Substances (GC/MS Fingerprint) after Liquid
h. Extraction of a Surgical Mesh Implant
i. Test for Bacterial Endotoxins using Limulus-Amoebocyte-Lysate (LAL-Test) – Kinetic
j. Turbidimetric Assay (KTA): Test for inhibition or enhancement with TiO2Mesh™
k. Transport simulation and packaging of TiO2Mesh™ - Validation Report
l. ETO Sterilization TiO2Mesh™ - Validation report

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing of the testing of the device was found to be acceptable and supports the claims of substantial equivalence and product safety and effectiveness assuming substantially equivalent technical characteristics are the basis for the safety and effectiveness of the device.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The TiO2Mesh™, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biocentw
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Re: K113311
Trade/Device Name: Ti02Mesh™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL, OXJ
Dated: June 01, 2011
Received: June 04, 2011

Dear Ms. Fisher:

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. 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): K113311

Device Name: TiO2Mesh™

Indications for Use:

TiO_2Mesh™ is a surgical mesh implant specifically indicated for repair of tissue defects of the abdominal wall, where a non-reabsorbable support material is required. Relevant applications include the repair of inguinal and incisional hernia in all common surgical methods. TiO_2Mesh™ can be used for both laparoscopic and other open procedures.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113311