K082941

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5.0 510(K) SUMMARY

Applicant Name:	Biomerix Corporation 47757 Fremont Boulevard Fremont, CA 94538 Phone: (510) 933-1222 Fax: (510) 933-3451
Contact Person:	Christina L Kichula Sr. Director, RA/QA/CA
Date Prepared:	October 1, 2008
Device Trade Name:	Biomerix Composite Surgical Mesh
Device Common Name:	Polymeric surgical mesh
Classification Name:	Mesh, surgical, polymeric
Predicate Devices:	Ethicon Prolene Soft Mesh (K001122) Ethicon Mersilene Polyester Fiber Mesh (pre-amendment) Biomerix Surgical Mesh (K070961) Bard Composix L/P Mesh (K061754) W.L. Gore GORETEX® DualMesh® Biomaterial (K992189) AMS InteMesh™ (K042592)
Device Description	Biomerix Composite Surgical Mesh is a non-absorbable porous polymer scaffold (polycarbonate polyurethane urea) incorporating knitted polypropylene monofilament fibers.
Intended Use	Biomerix Composite Surgical Mesh is intended to assist in the repair and/or reinforcement of hernia and other soft tissue defects requiring additional support of a nonabsorbable implant during and after wound healing.
Device Technological Characteristics and Comparison to Predicate Device(s):	The Biomerix Composite Surgical Mesh is similar in materials, design, performance and intended use to other surgical mesh devices. Any differences in the above characteristics have been adequately tested to support substantial equivalence.
Performance Data:	Material testing was performed to demonstrate that the material properties are suitable for the intended use. Bench testing was performed to demonstrate that the devices as manufactured meet the performance specifications. Test results demonstrate that the device meets the specifications and is acceptable for clinical

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use.

Extensive biocompatibility testing per ISO 10993-1 was performed to demonstrate that the material is safe and biostable.

Animal testing demonstrates that the mesh exhibits a well-tolerated long-term histomorphologic response with good integration with surrounding tissue, minimal foreign body response, and no evidence of device degradation or adjacent tissue necrosis.

Conclusion:

Based on the material, biocompatibility, bench, and animal testing, and the proposed device labeling, the Biomerix Composite Surgical Mesh is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomerix Corporation
% Ms. Christina L. Kichula
Sr. Director, RA, QA & CA
47757 Fremont Boulevard
Fremont, California 94538

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Re: K082941
Trade/Device Name: Biomerix Composite Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 16, 2008
Received: December 17, 2008

Dear Ms. Kichula:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

4.0 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K082941

Device Name: Biomerix Composite Surgical Mesh

Indications for Use:

Biomerix Composite Surgical Mesh is intended to assist in the repair and/or reinforcement of hernia and other soft tissue defects requiring additional support of a nonabsorbable implant during and after wound healing.

Prescription Use X 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)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082941