3.0 510(K) SUMMARY

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Applicant Name:	Biomerix Corporation 47757 Fremont Boulevard Fremont, CA 94538 Phone: (510) 933-3450 Fax: (510) 933-3451
Contact Person:	Maybelle Jordan VP, Regulatory Affairs & Business Development
Date Prepared:	December 22, 2011
Device Trade Name: Device Common Name: Classification Name:	Biomerix ASSURE™ Polymeric surgical mesh Mesh, surgical, polymeric
Predicate Devices:	Biomerix Ventral Hernia Repair Mesh (K093123) Atrium Advanta PTFE Facial Implant (K992991) Tissue Sciences Laboratories Permacol (K013625) Lifecell LTM-BPS Surgical Mesh (K082176)
Device Description:	Biomerix ASSURE is a sterile, composite mesh comprised of three layers: 1) a thin sheet of the Biomerix Biomaterial™, 2) a layer of knitted polypropylene monofilament fibers and 3) a resorbable lactide-caprolactone film. The resorbable film separates the permanent mesh from underlying tissues and organ surfaces, and it is designed to minimize the risk of tissue attachment to the device during the wound healing period. ASSURE is provided sterile for single use and is available as individually packaged thin sheets in various shapes and sizes.
Intended Use:	Biomerix ASSURE™ is intended for repair and/or reinforcement of soft tissues where weakness exists in plastic and reconstructive surgery. The resorbable protective film minimizes tissue attachment to the device.
Device Technological Characteristics and Comparison to Predicate Device(s):	The Biomerix ASSURE 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 use.

Biocompatibility testing in accordance to ISO 10993-1 recommended standards was conducted, and results demonstrated that the device is biocompatible according to these standards.

Animal testing demonstrates that the Biomerix ASSURE performs equivalently to a predicate device in terms of minimization of tissue attachment to the device and histological response.

Conclusion:

Based on the material, biocompatibility, bench, and animal testing, and the proposed device labeling, the Biomerix ASSURE 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomerix
% Ms. Maybelle Jordan
Vice President of Regulatory Affairs & Business Development
47757 Fremont Boulevard
Fremont, California 94538

DEC 23 2011

Re: K112567
Trade/Device Name: Biomerix ASSURE™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 20, 2011
Received: December 22, 2011

Dear Ms. Jordan:

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

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4.0 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K112567

Device Name: Biomerix ASSURE™

Indications for Use:

Biomerix ASSURE™ is intended for repair and/or reinforcement of soft tissues where weakness exists in plastic and reconstructive surgery. The resorbable protective film minimizes tissue attachment to the device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

David Krause for MKM

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

510(k) Number K112567