APPENDIX B 510(K) SUMMARY

Applicant Name:	Biomerix Corporation 1700 Rockville Pike, Suite 400 Rockville, MD 20852 Phone: (301) 998-6152 Fax: (301) 984-4368
	FEB 25 2008
Contact Person:	Christina L Kichula Director, RA/QA
Date Prepared:	February 13, 2008
Device Trade Name:	Biomerix Surgical Mesh
Device Common Name:	Polymeric surgical mesh
Classification Name:	Mesh, surgical, polymeric
Predicate Devices:	DePuy Restore® Orthobiologic Soft Tissue Implant, K031969 Artimplant AB Sportmesh™ (K052830) Ethicon Mersilene Polyester Fiber Mesh (pre-amendment) Zimmer Collagen Repair Patch (K053562) Biomerix Vascular Occlusion Device (K043371)
Device Description:	The Biomerix Surgical Mesh is a non-absorbable mesh manufactured from a polycarbonate polyurethane-urea matrix and standard polyester suture. The Biomerix Surgical Mesh is provided sterile for single use.
Intended Use:	The Biomerix Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery. The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair
Device Technological Characteristics and Comparison to Predicate Device(s):	The Biomerix 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 use. Extensive biocompatibility testing per ISO 10993-1 was performed to demonstrate that the material is safe and biostable. Animal testing demonstrates the ability of the mesh to support tissue ingrowth and mechanically reinforce the repair as compared to surgical controls, without any adverse clinical effects.
Conclusion:	Based on the material, biocompatibility, bench, and animal testing, and the proposed device labeling, the Biomerix 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

FEB 25 2008

Biomerix Corporation
% Ms. Christina L. Kichula, RAC
Director, RA/QA
1700 Rockville Pike, Suite 400
Rockville, Maryland 20852

Re: K070961
Trade/Device Name: Biomerix Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 13, 2008
Received: February 14, 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

APPENDIX A

Indications for Use

510(k) Number (if known): K070961

Device Name: Biomerix Surgical Mesh

Indications for Use:

The Biomerix Surgical Mesh is intended for the reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery.

The mesh is not intended to replace normal body structure or provide full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchor systems used to attach the tissue to the bone, provide mechanical strength for tendon repair.

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)

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

510(k) Number K070961