K052830 1/2

JAN 19 2006

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes Artimplant AB's summary for the Sportmesh™.

SUBMITTER'S NAME:	Artimplant AB
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DATE OF SUBMISSION:	October 4, 2005

1. **Identification of device**
   Proprietary Name: Sportmesh™
   Common Name: Surgical Mesh, RC Patch, Rotator cuff patch
   Classification Status: Class II per regulations 878.3300
   Product Code: FTM

2. **Equivalent devices**
   Sportmesh™ is substantially equivalent to:
   Organogenesis, Inc's FortaFlex™ Surgical Mesh (K042809)
   DePuy, Inc's Restore® Orthobiologic Soft Tissue Implant (K031969, K001738)
   Ethicon, Inc's ULTRAPRO™Mesh (033337)
   Davol's Marlex Mesh (pre-Amendments)

3. **Description of the Device**
   Sportmesh™is a knitted fabric made from ARTELON fibers. This construction permits the mesh to be cut into any desired shape or size without unraveling. The device is supplied in sheet form in sterile double layer peelable packaging.

4. **Intended use**
   Sportmesh™ is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. Sportmesh™ is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.

   Sportmesh™ is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide mechanical strength for the tendon repair. Sportmesh™ reinforces soft tissue and provides a degradable scaffold that is incorporated in the patient's own tissue.

5. **Comparison to predicate device.**
   Sportmesh™ is equivalent to the Organogenesis, Cuffpatch™ Surgical Mesh (K042809), DePuy, Inc's Restore® Orthobiologic Soft Tissue Implant (K031969),Ethicon, Inc's ULTRAPRO™Mesh (033337), Tissue Science's Permacol (K021056) and Davol's Marlex Mesh (pre-Amendments) with respect to intended use and technological characteristics.

6. **Discussion of performance testing.**
A collection of tests has been conducted and successfully completed including biocompatibility safety studies (ISO 10993 standards), and mechanical testing in accordance Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. The results demonstrate that Sportmesh™ provides appropriate mechanical properties for its use in soft tissue repair.

7. **Conclusion**
Based on comparison to the predicate devices, the Sportmesh™ is substantially equivalent to legally-marketed devices and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Artimplant AB
c/o Ms. Terry Sheridan Powell
Regulatory Consultant
M Squared Associates
719 A Street, NE
Washington, District of Columbia 20002

Re: K052830
Trade/Device Name: Artimplant AB Sportmesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 9, 2005
Received: December 12, 2005

Dear Ms. Powell:

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" (21CFR 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052830

Indications for Use

510(k) Number (if known): K052830

Device Name: Arbinplant AB Sportmesh

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K052830 Barbara Buehler for PAM

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

510(k) Number K052830