

SEP 18 2007

## SECTION 5. 510(K) SUMMARY

In accordance with 21 CFR 878.3300, the following information constitutes Artimplant AB's summary for the SportMesh™ /Artelon® Tissue Reinforcement.

### A. SUBMITTER INFORMATION

SUBMITTER'S NAME: Artimplant AB  
ADDRESS: Hulda Mellgrens gata 5, SE-421 32 Västra Frölunda, Sweden  
CONTACT PERSON: Ajrulla Zuta  
TELEPHONE NUMBER: +46 31 7465600  
FAX NUMBER: +46 31 7465660  
DATE OF SUBMISSION: 07/06/2007  
ESTABLISHMENT  
REGISTRATION  
NUMBER: 3004878714

### B. DEVICE IDENTIFICATION

DEVICE TRADE NAME: SportMesh™, Artelon® Tissue Reinforcement  
DEVICE COMMON NAME: Surgical Mesh  
CLASSIFICATION NAME: Surgical Mesh, Polymeric  
CLASSIFICATION REGULATION: 21 CFR 878.3300  
REGULATORY CLASS: Class II  
PRODUCT CODE: FTL  
ADVISORY PANEL: General and Plastic Surgery

### C. PREDICATE DEVICES

SportMesh™ / Artelon® Tissue Reinforcement is substantially equivalent to:

- K042809; CuffPatch™, Organogenesis Inc
- K071065; OrthADAPT™ Bioimplant, Pegasus Biologics
- K053562; Zimmer® Collagen Repair Patch, Tissue Science Laboratories
- K052830; SportMesh™, Artimplant AB

### D. DEVICE DESCRIPTION:

SportMesh™ / Artelon® Tissue Reinforcement is a knitted fabric made from Artelon® fibers. The construction permits the mesh to be cut into any desired shape or size without unraveling. The device is supplied sterile in sheet form in double layer peelable packaging.

### E. INTENDED USE:

SportMesh™ / Artelon® Tissue Reinforcement is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

SportMesh™ / Artelon® Tissue Reinforcement is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

SportMesh™ / Artelon® Tissue Reinforcement is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles,

biceps, or quadriceps tendons. 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™/ Artelon® Tissue Reinforcement reinforces soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.

## **F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

SportMesh™/ Artelon® Tissue Reinforcement is identical to the predicate Artimplant's SportMesh™ (K052830) with respect to its material composition. Each of the indications for use of the SportMesh™/ Artelon® Tissue Reinforcement device are shared by one or more of the predicate devices. Performance data demonstrate that SportMesh™/ Artelon® Tissue Reinforcement is technologically equivalent to one or more of the predicate devices, and that the SportMesh™/ Artelon® Tissue Reinforcement demonstrates performance characteristics that are equivalent to the predicate devices. Therefore, SportMesh™/ Artelon® Tissue Reinforcement is substantially equivalent to the predicate devices for the specified indications.

## **G. PERFORMANCE DATA**

A collection of tests has been conducted and successfully completed including biocompatibility safety studies (ISO 10993 standards), and mechanical testing in accordance with 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™/Artelon® Tissue Reinforcement provides appropriate mechanical properties for its use in soft tissue repair.

## **H. CONCLUSION**

Based on comparison to the predicate devices, SportMesh™/ Artelon® Tissue Reinforcement is substantially equivalent to legally marketed devices and presents no new concerns of safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 18 2007

Artimplant AB  
% M Squared Associates, Inc.  
Terry Sheridan Powell  
719 A Street, Northeast  
Washington, District of Columbia 20002

Re: K071887  
Trade/Device Name: SportMesh™/Artelon® Tissue Reinforcement  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: July 6, 2007  
Received: July 9, 2007

Dear Ms. Clark:

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.

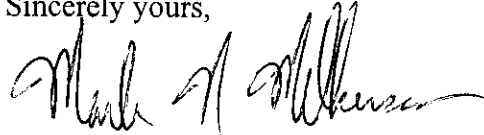
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

Enclosure

K071887

## SECTION 4. INDICATIONS FOR USE STATEMENT

### Indications for Use

510(k) Number (if known): K071887 to be assigned

Device Name: SportMesh™/ Artelon® Tissue Reinforcement

#### Indications for Use:

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SportMesh™/ Artelon® Tissue Reinforcement is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

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SportMesh™/ Artelon® Tissue Reinforcement reinforces soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.

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  K071887