K042809

1 of 1

NOV - 2 2004

510(K) Summary

Summary Date: February 25, 2004

Submitter's Information:
Organogenesis Inc.
150 Dan Road
Canton, MA 02021
Phone: 781-401-1110
Fax: 781-575-0440

Contact:
Seth Shapiro
Manager, Regulatory Affairs
Organogenesis Inc.
Phone: 781-401-1110
Fax: 781-575-0440

Device Trade Name: CuffPatch™

Device Common Name: Surgical Mesh

Classification Panel: General, Restorative and Neurological Devices

ntended Use: CuffPatch™ surgical mesh is intended for the reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.

CuffPatch™ surgical mesh is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair. CuffPatch™ surgical mesh reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To: CuffPatch™ is equivalent to the FortaFlex™ Surgical Mesh (CuffPatch™), K020049 and K011025, with respect to the materials, design, physical characteristics, performance characteristics and biological attributes. The subject device is also substantially equivalent to the Restore® Orthobiologic Soft Tissue Implant, K031969 in intended use and performance characteristics.

Device Description: CuffPatch™ consists of laminated sheets of porcine intestinal collagen. The collagen matrix is primarily Type I porcine collagen, and is free of cells and cell remnants. The product is supplied sterile in double-layered peelable packaging.

Performance Data: Evaluation of the device's materials, physical and performance characteristics revealed that CuffPatch™ is substantially equivalent to the predicate devices, and is suitable for its intended clinical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2004

Mr. Seth Shapiro
Manager, Regulatory Affairs
Organogenesis, Inc.
150 Dan Road
Canton, Massachusetts 02021

Re: K042809
Trade/Device Name: CuffPatch™ Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: October 8, 2004
Received: October 13, 2004

Dear Mr. Shapiro:

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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042809

Device Name: CuffPatch™ Surgical Mesh

Indications for Use:

CuffPatch™ surgical mesh is intended for reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.

CuffPatch™ surgical mesh is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair. CuffPatch™ surgical mesh reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue

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)

Miriam C. Provost

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

510(k) Number K042809

(Posted November 13, 2003)