DEC 1 8 2008

510(K) SUMMARY FOR COLLAGEN SCAFFOLD (CS) – K082079

Submission Prepared: 12/15/08

Applicant Information

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Device Information

Device Name:	ReGen Collagen Scaffold (CS)
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh, 21 CFR 878.3300
Classification Code:	FTM
Reviewing Panel:	Orthopedic Devices

Predicate Devices

- Restore Orthobiologic Implant, DePuy Orthopaedics, Inc. (K031969, K001738 and K982330);
- SIS Fistula Plug, Cook Biotech, Inc. (K050337);
- TissueMend, OrthoMend, TEI Biosciences, Inc. (K031188 and K051766);
- Surgisis Mesh, Cook Biotech, Inc. (K974540, K980431, K992159, K034039);
- BioBlanket Surgical Mesh, Kensey Nash, Corp. (K043259 and K041923);
- ZCR Patch, Permacol, Tissue Science Laboratories PLC (K992556, K013625, K021056, K043366, K050355);

- IMMIX Film, OsteoBiologics, Inc. (K024199 and K032673);
- SIS Plastic Surgery Matrix, Cook Biotech, Inc. (K034039)
- Sportmesh, Artimplant (K052830)
- Optimesh, Spineology, Inc. (K014200)
- Marlex Mesh, Davol, Inc. (Pre-amendment).

Device Description

The ReGen Collagen Scaffold (CS) is a resorbable collagen matrix comprised primarily of bovine type I collagen. The CS is provided in a semi-lunar shape with a triangular cross section to be used to reinforce weakened soft tissue and provide a resorbable scaffold that is replaced by the patient's own tissue. The surgeon trims the device to the size necessary for repair of the damaged or weakened soft tissue.

Intended Use

The ReGen Collagen Scaffold (CS) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CS is not a prosthetic device and is not intended to replace normal body structure.

Substantial Equivalence

The ReGen Biologics Collagen Scaffold (CS) has the same intended use and similar technological characteristics to the predicate surgical mesh devices, including; the DePuy Restore® Orthobiologic Soft Tissue Implant (K982330, K001738, K031969), the Cook Biotech SIS Fistula Plug (K050337), the TEI Biosciences TissueMend and OrthoMend (K031188, K051766), the Cook Biotech Surgisis Mesh, the Kensey Nash BioBlanket™ Surgical Mesh (K043259, K041923), the Tissue Sciences Laboratories' Permacol and ZCR Patch (K992556, K013625, K021056, K043366, K050355), the Organogenesis CuffPatch (K042809), the Cook Biotech SIS Plastic Surgery Matrix (K034039), the Artimplant Sportmesh (K052830) and the Spineology Optimesh (K014200). Any differences identified do not raise new types of safety or effectiveness questions. The questions common to all resorbable surgical meshes have been addressed in this

submission by biomechanical, biocompatibility, animal testing, and clinical studies with the device, including a prospective, randomized multicenter clinical trial that was conducted under an IDE.

This trial had two separately controlled and randomized arms; one arm consisted of 157 patients with no prior surgery to the involved meniscus (Acute) and the other 154 patients with one to three prior treatments to the involved meniscus (Chronic). Patients were followed for a mean of 59 months. Data from this IDE study and a publication in the July issue of the *Journal of Bone and Joint Surgery* analyzing the data from this multicenter clinical trial were used to support the substantial equivalence of this device. Data from this submission were presented at the November 14, 2008 meeting of the Orthopaedic and Rehabilitation Devices Panel Meeting for the purpose of providing FDA with advice and recommendations.

Based on the data presented, the CS is substantially equivalent to the predicate devices with respect to intended use, material of composition, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Mr. John Dichiara
ReGen Biologics
411 Hackensack Avenue
Hackensack, NJ 07601

Re: K082079
Regen Collagen Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OLC
Dated: July 22, 2008
Received: July 23, 2008

Dear Mr. Dichiara:

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) 276-0120. 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 Biometrics' (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,

Daniel G. Schultz, M.D., F.A.C.S.
Director
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082079

Device Name: ReGen Collagen Scaffold (CS)

Indications for Use:

The ReGen Collagen Scaffold (CS) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CS is not a prosthetic device and is not intended to replace normal body structure.

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