K061892

510(K) SUMMARY

NOV 2 2 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submitter:	CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, GA 30144 (770) 419-3355	**Contact Person:** John D. Ferros Director, Regulatory Affairs
Device Names:	Device Trade Name: Common/Usual Name: Proposed Classification Name:	ProPatch™ Soft Tissue Repair Matrix Surgical Mesh Surgical Mesh (Product Code: FTM)

Intended Use:

ProPatch™ Soft Tissue Repair Matrix is indicated for implantation to reinforce soft tissues where weakness exists including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures.

ProPatch™ Soft Tissue Repair Matrix is indicated for the reinforcement of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

ProPatch™ Soft Tissue Repair Matrix 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. ProPatch™ Soft Tissue Repair Matrix reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

Predicate Devices:

Device	Company	510 (k) Number(s), Clearance Date	Product Code
OrthADAPT™ Bioimplant	Pegasus Biologics 6 Jenner, Suite 150 Irvine, CA 92618	K043388 – 08/05/2005	FTM
Restore® Orthobiologic Soft Tissue Implant	Depuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581	K031969 – 07/28/2003 K001738 – 12/27/2000 K982330 – 09/25/1998	FTM

Device Description:

ProPatch™ Soft Tissue Repair Matrix is an acelluar bovine pericardia based surgical mesh. Product configurations consist of a 7 cm round and a 5 x 8 cm oval shapes, and configurations from 1 x 1 cm to 9 x 19 cm. Each surgical mesh is packaged ready to use within a clear peel-away inner pouch, and a foil laminate peel-away outer pouch. The packaged product is supplied sterile and non-pyrogenic.

Testing Supporting Substantial Equivalence:

Tissue biomechanics and functional performance testing of ProPatch™ was performed in accordance with the *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (revision: 03/02/1999). Results these tests demonstrate that the product has acceptable tensile strength, stiffness, tear resistance, suture retention strength, and burst strength. Biocompatibility testing was performed to meet the standards set forth in ISO10993 for a permanent implant and support suitable biocompatibility of the product. Intramuscular implants of the device were found to be non-irritating relative to the predicate control article.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

CryoLife, Inc.
% Mr. John D. Ferros
Manager, Regulatory Affairs
1655 Roberts Boulevard Northwest
Kennesaw, Georgia 30144

Re: K061892
Trade/Device Name: ProPatch™ Soft Tissue Repair Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXB, OXE, OXH, OWY
Dated: October 12, 2006
Received: October 13, 2006

Dear Mr. Ferros:

This letter corrects our substantially equivalent letter of November 22, 2006.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061892

Device Name: ProPatch® Soft Tissue Repair Matrix

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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)

David Krause -S