

ProPatch® Soft Tissue Repair Matrix
CryoLife, Inc.

JAN 10 2012

510(k) Summary

Submitter: CryoLife, Inc.
Contact: Kimberly DiCono
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Date: December 21, 2011
Trade Name: ProPatch® Soft Tissue Repair Matrix
Common Name: Surgical Mesh
Classification Name: Mesh, Surgical (21 CFR 878.3300, Product Code FTM)

Predicate Device: ProPatch® Soft Tissue Repair Matrix
K101587 – September 16, 2010
Product Code FTM
CryoLife, Inc.
1655 Roberts Blvd. NW
Kennesaw, GA 30144

Intended Use:

ProPatch® 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, hernias, suture-line reinforcement, and reconstructive procedures.

ProPatch® is indicated for the reinforcement, where weakness exists, of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including, but not limited to: reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Device Description:

ProPatch Soft Tissue Repair Matrix (ProPatch) is a surgical mesh manufactured from bovine pericardium. Decellularized tissues undergo chemical microbial reduction and viral inactivation processes, are inspected for freedom from defects, packaged, and terminally sterilized via gamma radiation.

ProPatch® Soft Tissue Repair Matrix
CryoLife, Inc.

ProPatch is comprised of a single tissue layer, nominally 0.6 mm thick, and is provided as a sterile and non-pyrogenic product that is fully hydrated and ready for use without the need for rinsing or rehydration prior to implantation.

Equivalence to Predicate Device:

The improved manufacturing process is very similar to the process by which the predicate device is manufactured. However, the improved process utilizes raw material (bovine pericardial) that are packed and shipped to the device manufacturer in a different manner. Additionally, process changes have been made to remove the use of antimicrobials, thereby eliminating concerns of patient sensitivity to potential residuals of these antimicrobials. Despite these minor changes to the process, the technical characteristics of the device are the same.

The equivalence of the biomechanical properties of the proposed device to the predicate device has been demonstrated through testing the characteristics identified below:

- Tensile Properties - the manner in which a material reacts to forces applied in tension.
- Tear Propagation Resistance - the ability of a material to resist tearing.
- Bursting Strength - the ability of a material to resist bursting due to pressure exerted on the material.
- Suture Retention Strength - the ability of a material to resist tearing from tension applied to suture that has been passed through the material.

The characteristics outlined above were tested and the biomechanical properties of the proposed device were found to be substantially equivalent to the biomechanical properties of the predicate device.

The decellularization efficiency of the improved process was demonstrated by evaluating the cellular content of finished devices. The decellularization observed was equivalent to that observed in the predicate device. Therefore, the decellularization efficiency of the improved process is equivalent to the process by which the predicate device is manufactured.

In summary, all testing demonstrates that the proposed device has the same technical characteristics as the predicate device.



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

CryoLife, Incorporated
% Ms. Kimberly DiCono
Senior Regulatory Affairs Specialist
1655 Roberts Boulevard, Northwest
Kennesaw, Georgia 30144

JAN 10 2012

Re: K110581
Trade/Device Name: ProtPatch® Soft Tissue Repair Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: December 21, 2011
Received: December 23, 2011

Dear Ms. DiCono:

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.

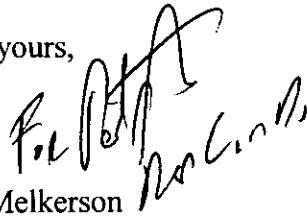
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ProPatch® Soft Tissue Repair Matrix
CryoLife, Inc.

Indications for Use

510(k) Number (if known): K110581

Device Name: ProPatch® Soft Tissue Repair Matrix

Indications for Use:

Non-Joint Related Repair

ProPatch 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, hernias, suture-line reinforcement, and reconstructive procedures.

Joint Related Repair

ProPatch is indicated for reinforcement where weakness exists, of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including, but not limited to: reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)

Daniel Krueger for MXM
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

CONFIDENTIAL

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