K101866

JUL 23 2010

510(k) Summary

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: CryoPatch® SG Pulmonary Human Cardiac Patch Common/Usual Name: Allograft Patch Classification Name: Intracardiac patch or pledget
Intended Use:	CryoPatch® SG Pulmonary Human Cardiac Patch is indicated for repair or reconstruction of the right ventricular outflow tract.

Predicate Devices:

Device	Company	510 (k) Number(s), Clearance Date	Product Code
CryoPatch® SG Pulmonary Human Cardiac Patch	CryoLife, Inc. Kennesaw, GA	K091626 – 08/07/2009	DXZ
CryoValve® SG Pulmonary Human Heart Valve (and Conduit).	CryoLife, Inc. Kennesaw, GA	K033484 – 02/07/2008 K083106 – 02/06/2009 K092021 – 05/25/2010	OHA

Device Description:
The CryoPatch® SG Pulmonary Human Cardiac Patch is derived from human pulmonary valve and artery tissue aseptically recovered from qualified donors. The patch is treated with an antimicrobial solution, and treated to remove the cells and cellular debris that have not already been removed during the post mortem period, harvesting, and the antimicrobial process. The patch is cryopreserved in a tissue culture medium, containing cryoprotectants, within the innermost pouch of a three pouch packaging system. The packaging system not only withstands ultra cold temperatures, but also allows for aseptic introduction of the patch into the operating room. Supercooling by liquid nitrogen boost is begun prior to crystallization to minimize ice crystal damage to the patch matrix. Finally, the patch is transferred for long term storage at or below -135° C.

CryoPatch® SG is distributed in three anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch.

Implantation of the CryoPatch SG Pulmonary Human Cardiac Patch reduces the risk for induction of HLA class I and class II alloantibodies, based on Panel Reactive Antibody measured at up to one year, compared to standard-processed pulmonary cardiac tissues. Data have not been provided to evaluate the effect of reduced HLA class I and class II alloantibodies on the long-term durability, or long-term resistance to rejection by the patient, of the CryoPatch SG.

Scientific Evidence and Bench Testing Supporting Substantial Equivalence:
A scientific analysis and testing of long-term storage of tissue (product stability) as well as long-term package integrity testing were conducted to change the device shelf life. These tests included, biomechanical properties testing, pulsatile flow characterization and accelerated wear testing. The scientific analysis provided theoretical and empirical (histological) evidence of tissue stability at cryogenic temperatures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 2 3 2010

CryoLife, Inc.
c/o Mr. John D. Ferros
Director, Regulatory Affairs
1655 Roberts Boulevard NW
Kennesaw, GA 30144

Re: K101866
Trade/Device Name: CryoPatch® SG Pulmonary Human Cardiac Patch
Regulation Number: 21 CFR 870.3470
Regulation name: Intracardiac Patch or Pledget
Regulatory Class: Class II
Product code: DXZ
Dated: July 1, 2010
Received: July 2, 2010

Dear Mr. Ferros:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101866

Device Name: CryoPatch® SG Pulmonary Human Cardiac Patch

Indications For Use: CryoPatch SG Pulmonary Human Cardiac Patch is indicated for repair or reconstruction of the right ventricular outflow tract

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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