FEB - 6 2009

K083106

510(K) SUMMARY (K083106)

This 510(k) Summary is 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: CryoValve® SG Pulmonary Valve
CryoValve® SG Pulmonary Valve and Conduit
Common/Usual Name: Human Heart Valve
Proposed Classification Name: Allograft Heart Valve (Product Code: OHA)

Intended Use:

CryoValve SG Pulmonary Human Heart Valves are indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. They may also be used in the replacement of native pulmonary valves when the Ross Procedure is performed. Pulmonary heart valve allografts are used to repair both congenital and acquired valvular lesions.

Predicate Devices:

Device	Company	510 (k) Number(s), Clearance Date	Product Code
CryoValve® SG Pulmonary Valve CryoValve® SG Pulmonary Valve and Conduit	CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, GA 30014	K033484 – February 07, 2008	OHA

Device Description:

The CryoLife, Inc. CryoValve SG Human Pulmonary Heart Valve (CryoValve SG) is a human heart valve aseptically recovered from qualified donors. The valve is dissected, treated with an antimicrobial solution, and treated to remove the cells and cellular debris that has not already been removed during the postmortem period, harvesting, and the antimicrobial process. The valve is cryopreserved in a tissue culture medium, containing a cryoprotectant, within the innermost pouch of a three pouch packaging system. The packaging system not only withstands ultracold temperatures, but also allows for aseptic introduction of the valve into the operating room. Supercooling by liquid nitrogen boost is begun prior to crystallization to minimize ice crystal damage to the valve matrix. Finally, the valves are transferred to a liquid nitrogen freezer for long-term storage at –135°C to –196°C.

Implantation of the CryoValve SG Pulmonary Human Heart Valve 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 the standard-processed pulmonary human heart valve. 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 CryoValve SG.

Analysis Supporting Substantial Equivalence:

A Clinical Data Analysis provides the needed assessment to support the product claim. The Analysis reviews previously published studies and furnishes the scientific rationale needed to make this change to the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

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

Re: K083106
CryoValve® SG Pulmonary Valve and CryoValve® SG Pulmonary Valve and Conduit
Regulatory Class: unclassified
Product Code: OHA
Dated: January 5, 2009
Received: January 6, 2009

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.

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,

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): K083106

Device Name: CryoValve® SG Pulmonary Valve and CryoValve® SG Pulmonary Valve and Conduit

Indications For Use: CryoValve® SG Pulmonary Human Heart Valves are indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. They may also be used in the replacement of native pulmonary valves when the Ross Procedure is performed. Pulmonary heart valve allografts are used to repair both congenital and acquired valvular lesions.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083106