K033484

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

FEB - 7 2008

Contact Person: David M. Fronk
Vice President, Regulatory Affairs and Quality Assurance

Device Names: Device Trade Name: CryoValve® SG Pulmonary Valve
CryoValve® SG Pulmonary Valve and Conduit
Common/Usual Name: Human Heart Valve
Proposed Classification Name: Heart Valve, Allograft (Product Code: 74MIE)

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, Concurrence Date	Product Code
Human Heart Valve Allograft - CryoValve	CryoLife, Inc. (Kennesaw, GA)	Distributed before June 26, 1991; therefore, no 510(k) or PMA on record	74 MIE

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.

Testing Supporting Substantial Equivalence:

CryoValve SG was subjected to preclinical bench and animal testing, as well as clinical evaluation, to assess biocompatibility, integrity, and mechanical performance. The performance of CryoValve SG was comparable to the predicate CryoValve, providing reasonable assurance of device performance for its intended use, and supporting a determination of substantial equivalence.

Substantial Equivalence:

The CryoLife, Inc. CryoValve SG Human Heart Valve (CryoValve SG) is substantially equivalent to the predicate devices and predicate human tissue for implantation in commercial distribution, having similar indications for use, material composition, method of processing/manufacture, technological characteristics, and final packaging. This determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act is not intended to have any bearing on the resolution of intellectual property infringement litigation or other matters related to intellectual property.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2008

Mr. David M. Fronk
Vice President, Regulatory Affairs
and Quality Assurance
CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144

Re: K033484
Trade/Device Name: CryoValve® SG Pulmonary Human Heart Valve and
CryoValve® SG Pulmonary Human Heart Valve and Conduit
Regulatory Class: Unclassified
Product Code: OHA
Dated: September 7, 2007
Received: September 10, 2007

Dear Mr. Fronk:

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.

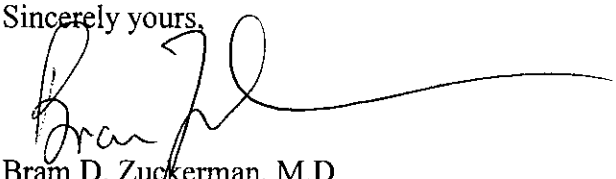
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Biometric's (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): K033484

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 X 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted] Brian Ladwig

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033484