December 4, 2017

CryoLife, Inc.
John Ferros
Senior Director, Regulatory Affairs
1655 Roberts Blvd. NW
Kennesaw, Georgia 30144

Re: K172085
Trade/Device Name: PhotoFix Decellularized Bovine Pericardium
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PSQ
Dated: November 2, 2017
Received: November 3, 2017

Dear John 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172085

Device Name
PhotoFix Decellularized Bovine Pericardium

Indications for Use *(Describe)*
PhotoFix is indicated for the following uses: intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels and arteriovenous access revisions).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K172085

510(k) Summary

Date: December 1, 2017

Submitter: CryoLife, Inc.

Address: 1655 Roberts Blvd. NW
Kennesaw, GA 30144

Phone: 770-419-3355

Fax: 770-590-3783

Contact: Heather Emerick
Manager, Regulatory Affairs

Device Trade Name: PhotoFix® Decellularized Bovine Pericardium

Classification: Class II
21 CFR 870.3470- Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.

Product Code: PSQ- Intracardiac patch or pledget, biologically derived

Predicate Device Information

Device Name(s)	Manufacturer(s)	510(k) Number(s)	Product Code(s)
PhotoFix® Decellularized Bovine Pericardium	CryoLife, Inc.	K162506	DXZ
XenoSure® Biological Patch (formerly PeriPatch)	LaMaitre Vascular, Inc.	K040835	DXZ/FTM
CorMatrix® ECM for Cardiac Tissue Repair	CorMatrix Cardiovascular, Inc.	K063349	DXZ

Device Description

The PhotoFix® Decellularized Bovine Pericardium ("PhotoFix") is a cardiovascular patch that is prepared from bovine pericardium, stabilized using dye-mediated photooxidation, processed using ethylene oxide, and sterilized using aseptic processing techniques. The photooxidation process creates crosslinks in the bovine tissue. No aldehyde chemistry is used during any phase of manufacturing including the tissue fixation or sterilization processes.

PhotoFix is intended for single use only and cannot be resterilized. PhotoFix is supplied sterile in a sealed container with 22% buffered ethanol solution. Rinsing of the pericardium prior to implantation is not required.

Indications for Use

PhotoFix is indicated for the following uses: intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels and arteriovenous access revisions).

Substantial Equivalence to Predicate Devices

Comparative testing was performed between PhotoFix and both XenoSure (K040835) and CorMatrix ECM for Cardiac Tissue Repair (K063349) to evaluate the following biomechanical properties: Suture Retention Strength, Ultimate Tensile Strength, Burst Strength and Tear Resistance. Testing demonstrated that PhotoFix is substantially equivalent to the identified predicate devices. The table below outlines the technological characteristics of PhotoFix Decellularized Bovine Pericardium and the predicate devices.

	PhotoFix Decellularized Bovine Pericardium	**PhotoFix Decellularized Bovine Pericardium**	**XenoSure Biological Patch** ***(formerly PeriPatch)***	**CorMatrix ECM for Cardiac Tissue Repair**
510(k) Number	K172085	K162506	K040835	K063349
Indications for Use	Intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels and arteriovenous access revisions).	Intracardiac repair, great vessel repair, suture line buttressing and pericardial closure.	A surgical patch material for cardiac and vascular reconstruction and repair, soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.	An intracardiac patch or pledget for tissue repair (i.e., atrial septal defect (ASD), ventricular septal defect (VSD), etc.) and suture line buttressing.
Material	Photooxidized Bovine Pericardium	Photooxidized Bovine Pericardium	Glutaraldehyde-Fixed Bovine Pericardium	Porcine Small Intestinal Submucosa (SIS) ECM
Application	Single-layer	For applications exposed to peak systolic pressure, use a reinforced patch technique (i.e., minimum of double thickness)	Single-layer	Single-layer
Sterilization Method	Processed using ethylene oxide; sterilized using aseptic processing techniques	Processed using ethylene oxide; sterilized using aseptic processing techniques	Liquid chemical sterilized; sterilized using aseptic processing techniques	Sterilized using ethylene oxide gas

Conclusion:

PhotoFix is substantially equivalent to the predicate devices PhotoFix Decellularized Bovine Pericardium (K162506), CorMatrix ECM for Cardiac Tissue Repair (K063349), and XenoSure Biological Patch (K040835).