February 14, 2019

CryoLife, Inc.
Heather Emerick
Regulatory Affairs Manager
1655 Roberts Blvd. NW
Kennesaw, Georgia 30144

Re: K183635
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: February 8, 2019
Received: February 11, 2019

Dear Ms. Emerick:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Rachel E. Neubrander -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)*

K183635

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: February 14, 2019

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

Type of 510(k): Special 510(k)

Predicate Device Information

Device Name	Manufacturer	510(k) Number	Product Code
PhotoFix® Decellularized Bovine Pericardium	CryoLife, Inc.	K172085	PSQ

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).

Comparison to Predicate Device

PhotoFix Decellularized Bovine Pericardium is serving as its own predicate device. PhotoFix Decellularized Bovine Pericardium is substantially equivalent to the currently marketed device (K172085) in regards to intended use, processing method, sterilization method and technological characteristics with the exception of the packaging of the 8x14cm patch configuration which is the focus of this Special 510(k) submission. The 8x14cm patch configuration will be packaged in a 250mL final packaging bottle; all other PhotoFix patch configurations are packaged in a 125mL final packaging bottle.

A risk analysis has been performed and all design verification and design validation activities have been identified and completed in conformance with design control requirements. Based on the qualification activities of the new 250mL bottle, the shelf life requirement of the 8x14cm patch configuration will be identified as a minimum of 1 year.

Non-Clinical Testing

In order to demonstrate substantial equivalence between the existing 125mL bottle and the proposed 250mL bottle, the following testing was performed:

- Simulated Distribution testing followed by Bacterial Aerosol Challenge testing
- Accelerated Aging Shelf Life testing followed by Bacterial Aerosol Challenge testing

Conclusion:

PhotoFix Decellularized Bovine Pericardium is substantially equivalent to the predicate device currently on the market (K172085).