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. 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
contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the
Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)
796-7100 or at its Internet address

Sincerely,

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

Enclosure
Indications for Use

PhotoFix Decellularized Bovine Pericardium is indicated for the following uses: intracardiac repair, great vessel repair, suture line buttressing and pericardial closure.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“If 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.”
Date: March 9, 2016
Submitter: CryoLife, Inc.
Address: 1655 Roberts Blvd., N.W.
          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: DXZ – Patch, Pledget and Intracardiac, PETP, PTFE, Polypropylene

Predicate Device Information:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Company</th>
<th>510(k) Clearance</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulzer CarboMedics CardioFix</td>
<td>Sulzer CarboMedics</td>
<td>K993288</td>
<td>DXZ</td>
</tr>
<tr>
<td>Pericardium</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sulzer CarboMedics CardioFix Pericardium was originally cleared under K993288 in 1999. Subsequently, the device name changed to PhotoFix Decellularized Bovine Pericardium.

Device Description

The PhotoFix® Decellularized Bovine Pericardium (“PhotoFix”) is a cardiovascular patch prepared from bovine pericardium which is stabilized using a dye-mediated photooxidation process, 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 plastic container with 22% buffered ethanol solution. The package is designed to facilitate convenient aseptic transfer of the pericardium into the sterile field. Rinsing of the pericardium prior to implantation is not required.

Model Numbers and Configurations:

<table>
<thead>
<tr>
<th>Catalog Number(s)</th>
<th>Size(s) (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFP 1x1</td>
<td>1cm x 1cm</td>
</tr>
<tr>
<td>PFP 4x4</td>
<td>4cm x 4cm</td>
</tr>
<tr>
<td>PFP 6x8</td>
<td>6cm x 8cm</td>
</tr>
<tr>
<td>PFP 8x14</td>
<td>8cm x 14cm</td>
</tr>
<tr>
<td>PFP 10x16</td>
<td>10cm x 16cm</td>
</tr>
<tr>
<td>PFP 14x16</td>
<td>14cm x 16cm</td>
</tr>
</tbody>
</table>

Indications for Use:

PhotoFix® Decellularized Bovine Pericardium is indicated for the following uses: intracardiac repair, great vessel repair, suture line buttressing and pericardial closure.

Substantial Equivalence to Predicate/ Technological Characteristics:

Following to the clearance of K993288, the CardioFix Pericardium name changed to PhotoFix Decellularized Bovine Pericardium. PhotoFix Decellularized Bovine Pericardium is substantially equivalent to the identified predicate, CardioFix Pericardium (K993288), in regards to material, processing method, sterilization method, packaging solution, and storage. The table below provides a summary of the differences between the CardioFix and PhotoFix indications for use. The differences in the Indications for Use statement between PhotoFix Decellularized Bovine Pericardium and the originally cleared device, the predicate, do not affect the safety and effectiveness of the device when used as labeled.

<table>
<thead>
<tr>
<th>K993288</th>
<th>K162506</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulzer Carbomedics CardioFix Pericardium is indicated for the following uses:</td>
<td>PhotoFix Decellularized Bovine Pericardium is indicated for the following uses:</td>
</tr>
<tr>
<td>• Intracardiac Repair</td>
<td>Intracardiac repair, great vessel repair, suture line buttressing and pericardial closure.</td>
</tr>
<tr>
<td>• Ventricular Repair using a reinforced patch technique (i.e., minimum of double thickness)</td>
<td></td>
</tr>
<tr>
<td>• Atrial Repair</td>
<td></td>
</tr>
<tr>
<td>• Great vessel repair and suture line buttressing using a reinforced patch technique (i.e., minimum of double thickness) for applications exposed to peak systolic pressure</td>
<td></td>
</tr>
<tr>
<td>• Pericardial closure.</td>
<td></td>
</tr>
</tbody>
</table>
In addition, the packaging material of the storage jar changed from glass to a polymer.

**Performance Testing**

The following performance tests were conducted to support the change:
- Chemical characterization testing
- Biocompatibility testing (cytotoxicity and hemolysis)
- Packaging shelf-life

The results of the testing demonstrated that the packaging is non-cytotoxic, non-hemolytic, and maintains a sterile barrier. The packaging is equivalent to the predicate device.

**Conclusion:**

PhotoFix is substantially equivalent to the respective predicate device, CardioFix Pericardium.