AUG 5 - 2005

K051916
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4. 510(k) Summary

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|---|---|
| **Sponsor:** | CryoVascular Systems, Inc.<br>160 Knowles Drive<br>Los Gatos, CA 95032 |
| **Contact Person:** | Elaine Aplaon |
| **Phone Number:** | 408 866 3204 |
| **Fax Number:** | 408 376 3677 |
| **Prepared:** | July 12, 2005 |
| **Trade Name:** | PolarCath™ Peripheral Dilatation System |
| **Common Name:** | Percutaneous Transluminal Angioplasty Catheter |
| **Classification:** | II |
| **Product Code:** | LIT/DQY<br>21 CRF 870.1250 |
| **Predicate Devices:** | PolarCath Peripheral Dilatation System |

**Device Description**
The PolarCath Peripheral Dilatation System consists of a Catheter, Inflation Unit, connecting cable and a rechargeable battery pack with recharging unit and battery receptacle. The inflation medium (liquid nitrous oxide) is provided in a disposable 14 gram cartridge.

**Indications for Use**
The PolarCath Peripheral Dilatation System is indicated to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or arteriovenous dialysis fistulae. The PolarCath Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.

**Substantial Equivalence**
The PolarCath Peripheral Dilatation System design, materials, manufacturing process and intended use are substantially equivalent to the predicate device and other marketed PTA catheters.

**Performance Data**
The safety and effectiveness of the modified PolarCath Peripheral Dilatation System is demonstrated with design control activities and bench testing on file at CryoVascular Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

CryoVascular Systems, Inc.
c/o Ms.Elaine Aplaon
160 Knowles Drive
Los Gatos, CA 95032

Re: K051916
Trade/Device Name: PolarCath™ Peripheral Dilation System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: July 14, 2005
Received: July 15, 2005

Dear Ms. Aplaon:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bahner

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

Enclosure

3. 510(k) Indications for Use



510(k) Number (if known): K051916

Device Name: PolarCath™ Peripheral Dilatation System

Indications for use:

The PolarCath Peripheral Dilatation System is indicated to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or native arteriovenous dialysis fistulae. The PolarCath Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Donna R Vochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051916