K042230

NOV - 5 2004

4. 510(k) Summary

Sponsor:	CryoVascular Systems, Inc. 160 Knowles Drive Los Gatos, CA 95032
Contact Person:	Kim Tompkins
Phone Number:	408 866 3203
Fax Number:	408 376 3677
Prepared:	August 13, 2004
Trade Name:	PolarCath™
Common Name:	Percutaneous Transluminal Angioplasty Catheter
Classification:	II
Product Code:	LIT 21 CFR 870.1250
Predicate Devices:	PolarCath Peripheral Balloon Catheter System

Device Description
The PolarCath Peripheral Balloon Catheter System consists of a Peripheral Balloon 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 cylinder.

Indications for Use
The PolarCath™ Peripheral Dilatation System is indicated to dilate stenosis in the peripheral vasculature (subclavian, renal, iliac, femoral, popliteal, and infrapopliteal 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.

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
In vitro testing demonstrated that the PolarCath Peripheral Balloon Catheter System met all acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

CryoVascular Systems, Inc.
c/o Ms. Kim Tompkins
Sr. Director of Clinical and Regulatory Affairs
160 Knowles Drive
Los Gatos, CA 95032

Re: K042230
PolarCath™ Peripheral Dilatation System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 16, 2004
Received: August 17, 2004

Dear Ms. Tompkins:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

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): K042230

Device Name: PolarCath™ Peripheral Balloon Catheter System

Indications for use:

The PolarCath™ Peripheral Dilatation System is indicated to dilate stenosis in the peripheral vasculature (subclavian, renal, iliac, femoral, popliteal, and infrapopliteal 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 in self-expanding peripheral vascular stents.

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) number K042230