



Food and Drug Administration
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October 26, 2015

NuCryo Vascular, LLC
% Michael Billig
Regulatory Consultant
Experien Group, LLC
755 N. Mathilda Ave, Suite 100
Sunnyvale, CA 94085

Re: K152665

Trade/Device Name: PolarCath Peripheral Dilatation System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: September 16, 2015
Received: September 17, 2015

Dear Mr. Billig:

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

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152665

Device Name
PolarCath Peripheral Dilatation System

Indications for Use (Describe)

The PolarCath Peripheral Dilatation System's intended use is for the dilatation of 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.

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.

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510(k) Summary

K152665

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GENERAL INFORMATION

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Date Prepared: September 17, 2015

DEVICE INFORMATION

Device Name:

PolarCath Peripheral Dilatation System

Common or Usual Name:

Catheter, Percutaneous

Classification Name:

21 CFR§870.1250, Percutaneous catheter

Regulatory Class:

Class II

Product Code:

LIT/DQY

PREDICATE DEVICE(S)

- PolarCath Peripheral Dilatation System (K092455)

This predicate has not been subject to a design-related recall.

INDICATIONS FOR USE

The PolarCath Peripheral Dilatation System's intended use is for the dilatation of 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.

The Indications for Use statement for the PolarCath Peripheral Dilatation System is identical to the predicate device.

PRODUCT DESCRIPTION

The PolarCath™ Peripheral Dilatation System (PolarCath System) consists of a disposable catheter, a reusable Cryoplasty inflation unit, a disposable nitrous oxide cartridge, and a disposable catheter extension.

The PolarCath System is designed for dilatation of stenotic lesions in peripheral arteries. The procedure consists of inserting a catheter over a guidewire to the target lesion, attaching the catheter to the catheter extension, attaching the catheter extension to the Inflation Unit, inserting a nitrous oxide cartridge into the Inflation Unit, and inflating the balloon catheter for a set time at a set pressure, using the controls on the Inflation Unit.

The Cryoplasty inflation unit functions to: a) deliver the inflation media (liquid nitrous oxide) to the balloon; b) control the pressure inside the inner balloon; c) provide a vacuum between the inner and outer balloons; and d) control the length of time for delivery of the inflation media which is manually extracted at the end of the inflation time. The inflation unit monitors the temperature inside the balloon. Excess pressure is prevented by the presence of a relief valve in the inflation unit.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the PolarCath System are similar to the predicate device. Available performance data support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the proposed device is substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the PolarCath System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the PolarCath System to support a determination of substantial equivalence to the predicate device. The following table lists the non-clinical testing performed and the results for each test.

Testing Type	Test Description	Result
Performance Bench Testing	The nonclinical testing assessed the following aspects of the device: <ul style="list-style-type: none"> • Catheter Extension Verification Testing • Inflation Unit Verification • Simulated Use • Transit Testing 	The PolarCath System passed all functional testing and met all product specification requirements and demonstrated equivalent performance to the predicate device.
Software Verification Validation Testing	PolarCath System Software Testing (The Level of Concern for PolarCath System software was determined to be “Moderate”.)	PolarCath System Software met all requirements of the SRS.
Electromagnetic Compatibility and Electrical Safety	Testing in accordance with the following standards: <ul style="list-style-type: none"> • IEC 60601-1:2005 • IEC 60601-1-2:2007 	The PolarCath System met all acceptance criteria in accordance with: <ul style="list-style-type: none"> • IEC 60601-1:2005 • IEC 60601-1-2:2007

The collective results of performance testing demonstrate that the materials chosen, the manufacturing processes, and design of the PolarCath System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the PolarCath System does not raise new questions of safety or effectiveness when compared to the predicate device.

CONCLUSION

As demonstrated in the nonclinical testing summaries, no new issues of safety or effectiveness are raised by using the PolarCath System to dilate stenotic lesions in the peripheral vasculature. No animal or clinical testing was required.

SUMMARY

The PolarCath Peripheral Dilatation System is substantially equivalent to the predicate device.