K023463

FEB 19 2003

510(k) Summary
CryoVascular Systems, Incorporated
CVSi™ Peripheral Balloon Catheter System

This 510(k) summary for the CVSi™ Peripheral Balloon Catheter System is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

GENERAL INFORMATION

Manufacturer:

CryoVascular Systems, Inc.
160 Knowles Drive
Los Gatos, California 95032
(408) 376-3675 (phone)
(408) 376- 3677 (fax)
Est. Reg. No. (to be applied for)

Contact Person:

R. Michael Crompton
Vice President, Regulatory / Clinical Affairs
and Quality Assurance

DEVICE DESCRIPTION

Classification: Class II

Trade Name: CVSi™ Peripheral Balloon Catheter System

Generic/Common Name: Balloon Dilatation Catheter (21 CFR § 870.1250)
Injector and Syringe, Angiographic (21 CFR § 870.1650)

PREDICATE DEVICES

(1) CVSi Peripheral Balloon Catheter System; CryoVascular Systems, Inc. (K022061)
(2) OPTA LP PTA Catheter; Cordis/A Johnson & Johnson Company (K971448)

INTENDED USE

The CVSi™ Peripheral Balloon Catheter and the CVSi™ Catheter Inflation Unit are indicated for percutaneous, transluminal angioplasty of stenotic lesions in superficial femoral and popliteal arteries.

DEVICE DESCRIPTION

The CVSi™ Peripheral Balloon Catheter System consists of a CVSi™ Peripheral Balloon Catheter, CVSi™ 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.

SUBSTANTIAL EQUIVALENCE

The CVSi Peripheral Balloon Catheter System is substantially equivalent to the predicate devices identified previously. The CVSi Peripheral Balloon Catheter System is substantially equivalent to the predicate devices with regard to intended use, function, materials, and sterilization method.

Testing performed on the CVSi Peripheral Balloon Catheter System demonstrates the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness with respect to balloon dilatation catheters.

FUNCTIONAL PERFORMANCE TESTING

Functional testing was conducted on the CVSi Peripheral Balloon Catheter System to ensure that the product will function according to its Instructions for Use. All testing conducted confirmed the acceptability of the CVSi Peripheral Balloon Catheter System to perform as intended.

BIOCOMPATIBILITY EVALUATION

Biocompatibility testing was conducted on the CVSi Peripheral Balloon Catheter System materials to ensure acceptability when used as directed. The CVSi Peripheral Balloon Catheter System materials passed the necessary biocompatibility tests, in conformance with ISO 10993-1, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for an External Communicating Device in contact with Circulating Blood for a contact duration of A-Limited (< 24 hours).

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the CVSi Peripheral Balloon Catheter System to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Cryovascular Systems, Inc.
c/o Mr. R. Michael Crompton
Vice President, Regulatory/Clinical Affairs
and Quality Assurance
160 Knowles Drive
Los Gatos, CA 95032

Re: K023463
Trade Name: CVSi™ Peripheral Balloon Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Balloon Dilatation Catheter
Regulatory Class: Class II (two)
Product Code: DQY, LIT
Dated: December 16, 2002
Received: December 23, 2002

Dear Mr. Crompton:

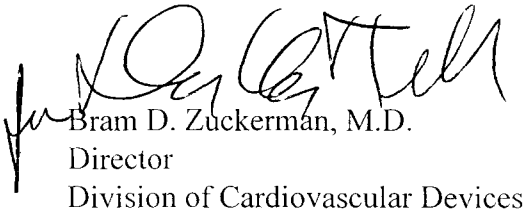
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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

Enclosure

Statement of Indications for Use

510(k) Number (if known): K023463

Device Name: CVSi™ Peripheral Balloon Catheter System

Indications for Use: The CVSi™ Peripheral Balloon Catheter and the CVSi™ Catheter Inflation Unit are indicated for percutaneous, transluminal angioplasty of stenotic lesions in the superficial femoral and popliteal arteries. The CVSi™ Peripheral Balloon Catheter System is not indicated for use in other vasculature, including coronary arteries, carotid arteries, synthetic vascular grafts, and vein grafts. The CVSi™ Peripheral Balloon Catheter System is not indicated for stent delivery or stent expansion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023463

Prescription Use X OR Over-the-Counter Use_____
(Per 21 C.F.R. § 801.109)