OCT 29 2009

K092361

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Applicant: Invatec S.p.A.
Via Martiri della Libertá, 7
25030 Roncadelle (Brescia) Italy
Peter Muster PhD, VP QA & RA Invatec S.p.A.
Tel: +39 030 258 93 11
Fax: +39 030 258 93 12
Email: Peter.Muster@invatec.com

Contact Person: John Clay, Director, QA&RA
Invatec Inc., US
Emrick Blvd. 3101, Suite 113
Bethlehem, PA 18020
Tel: (610) 625-1429
Fax: (610) 625-1436
Email: john.clay@invatec-us.com

Date Prepared: July 30, 2009

Device Information

Trade Name: REEF HP 0.035" OTW PTA Balloon Dilatation Catheter
Common Name: Percutaneous Transluminal Angioplasty Catheter
Regulation Name: Percutaneous Catheter

Predicate Devices

- Invatec Admiral Extreme 0.035" OTW PTA Balloon Dilatation Catheter (K062809)
- Cordis Powerflex Extreme PTA Balloon Catheter (K032737)

Device Description

The Reef HP 0.035"OTW PTA Balloon Catheter is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter consisting of a proximal hub, dual lumen shaft, and a distal non-compliant dilatation balloon. The REEF HP 0.035" OTW PTA Balloon Dilatation Catheter is compatible with guidewires with a maximum diameter of 0.035" and with 5, 6 or 7 FR introducer sheaths, depending on the diameter/length of the

dilatation balloon. The catheter is provided in useable catheter lengths of 50 cm, 80cm and 120 cm.

Indication for Use

The REEF HP 0.035" OTW PTA Balloon Dilatation Catheters are intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics

The REEF HP 0.035" OTW PTA Balloon Dilatation Catheter have the same or similar design, materials and fundamental technology as the previously cleared Admiral Extreme 0.035" OTW PTA Balloon Dilatation Catheters. In addition, the REEF HP 0.035" OTW PTA Balloon Dilatation Catheter has Rated Burst Pressures (RBP) similar to the Cordis Powerflex Extreme PTA Balloon Catheter, and other PTA catheters.

Performance Data

Bench testing of the REEF HP 0.035" OTW PTA Balloon Dilatation Catheter demonstrated that the device met the bench test acceptance criteria. Biocompatibility testing was performed in accordance with ISO 10993-Part 1.

Conclusion

Based on the same intended use, technological characteristics, and performance characteristics, Invatec believes the REEF HP 0.035" OTW PTA Balloon Dilatation Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Invatec, Inc., US
c/o Mr. John Clay
Director of Regulatory Affairs and Quality
3101 Emrick Boulevard, Suite 113
Bethlehem, PA 18020

OCT 2 9 2009

Re: K092361
REEF HP 0.035" OTW PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: July 30, 2009
Received: August 4, 2009

Dear Mr. Clay:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

M. A. Hillebrenner

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): K092361

Device Name: REEF HP 0.035" OTW PTA Balloon Dilatation Catheter

Indications for Use:

The REEF HP 0.035" OTW PTA Balloon Dilatation Catheters are intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092361