NOV - 8 2004

K042538
page 1 of 2

510(k) Summary
SAILOR PLUS Percutaneous Transluminal Angioplasty (PTA) Catheter

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant (Manufacturer)	Invatec Innovative Technologies Via Martiri della Libertà, 7 25030 Roncadelle (BS) Italy Tel: +39 030 258 93 11 Fax: +39 030 258 93 12 www. invatec.com info@invatec.com
Submitter	**ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398 7000 Fax: (763) 398 7200
Contact Person	Mike Winegar Tel: (763) 398-7225 Fax: (763) 398-7200 E-mail: mwinegar@ev3.net
Date Prepared	September 17th 2004
Device Trade Name	SAILOR PLUS Percutaneous Transluminal Angioplasty (PTA) Catheter
Device Common Name	Peripheral Transluminal Angioplasty (PTA) Catheter
Classification Name	21 CFR 870.1250 Percutaneous Catheter
Device Classification	Regulatory Class: Class II Product Code: LIT
Classification Panel	Cardiovascular
Predicate Device	Cordis OPTA™ PRO Balloon Dilatation Catheter
Intended use	The SAILOR PLUS PTA Balloon Dilatation Catheter is 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.
Device Description	The SAILOR PLUS Balloon Dilatation Catheter is OTW PTA catheter with a semi-compliant inflatable balloon mounted at the distal tip. It has a dual lumen catheter with a guidewire lumen and a balloon inflation lumen. Two radiopaque markers indicate the dilating portion of the balloon and help in correctly positioning the balloon within the vessel. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses. The maximum recommended guidewire diameter is 0.035". The device is available in balloon diameters of 3-12mm, balloon lengths of 20, 40, 60, 80 and 120mm and catheter lengths of 130, 80 and 40cm.

K042538
page 2 of 2

Biocompatibility	All material used in SAILOR PLUS Percutaneous Transluminal Angioplasty (PTA) Catheter are biocompatible based on the biocompatibility testing.
Performance data	In vitro testing was conducted to demonstrate the safety and effectiveness of SAILOR PLUS Percutaneous Transluminal Angioplasty (PTA) Catheter. The testing included balloon compliance, balloon burst pressure, balloon fatigue, shaft burst pressure, bond strength, catheter dimensions and guidewire and introducer compatibility.
Summary of Substantial Equivalence	The SAILOR PLUS Balloon Dilatation Catheter is similar to the predicate with respect to intended use and to physical characteristics, such as catheter and balloon dimensions and catheter design and materials. Further, the mechanical and biocompatibility testing data is indicative of the safety and effectiveness of SAILOR PLUS Balloon Dilatation Catheter.
Conclusion	SAILOR PLUS Balloon Dilatation Catheter is substantially equivalent to the Predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Invatec Innovative Technologies
c/o Mr. Mike Winegar
Vice President, International RA
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442

Re: K042538
SAILOR PLUS™ Percutaneous Transluminal Angioplasty (PTA) Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 17, 2004
Received: September 20, 2004

Dear Mr. Winegar:

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) 594-4648. 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,

B Zuckerman 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: K042538

Device Name: SAILOR™ PLUS PTA Balloon Dilatation Catheter

Indications For Use:

The SAILOR™ PLUS PTA Balloon Dilatation Catheter is 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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Chambers

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042538