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2.5 *510(k) Summary*

OPTIMUS 0.035" PTA Balloon Dilatation Catheter

This Special 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.5.1

General Information

Submitter:	USCI Ireland IDA Business Park, Ballinasloe, Co. Galway, Ireland
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Contact Person:	Ailish O'Reilly
Summary Preparation Date:	September 4th 2008

2.5.2 **Device Information**

Device Name:	OPTIMUS 0.035" PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Dilatation Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code: DQY)

2.5.3 **Predicate Devices**

Device Name:	OPTIMUS 0.035" PTA Balloon Dilatation Catheter
510(k) Clearance Number:	K072156
Device Name:	Cordis OPTA PRO PTA Catheter
510(k) Clearance Number:	K032737
Device Name:	Invatec SAILOR PLUS PTA Catheter
510(k) Clearance Number:	K042538

2.5.4 Device Description

The OPTIMUS 0.035" PTA Balloon Dilatation Catheter is a two lumen catheter with a distal inflatable balloon. One lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. Two radiopaque marker bands indicate the dilatating section of the balloon and aid in the balloon placement. The marker bands also indicate the stated nominal length of the balloon. The catheter tip is designed to ease entry into the indicated arteries and to facilitate the crossing of tight stenoses.

2.5.5 Indications for Use

The OPTIMUS 0.035" PTA Balloon Dilatation Catheter is intended to dilate stenoses in the Iliac, Femoral, Popliteal and Renal arteries.

2.5.6 Performance Data

Substantial equivalence of the OPTIMUS 0.035" PTA Balloon Dilatation Catheter to the predicate device has been demonstrated through data collected from non-clinical design verification/ validation tests and analyses. The device has been tested according to ISO 10993 Part 1 and was determined to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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USCI Ireland
c/o Ms. Ailish O'Reilly
IDA Business Park
Ballinasloe
Co. Galway
Ireland

Re: K082646
OPTIMUS 0.035" PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (2)
Product Code: DQY
Dated: October 2, 2008
Received: October 7, 2008

Dear Ms. O'Reilly:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

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

Enclosure

2.4 *Indications for Use*

510(k) Number: K082646

Device Name: OPTIMUS 0.035" PTA Balloon Dilatation Catheter

Indications for Use:
The OPTIMUS 0.035" PTA Balloon Dilatation Catheter is intended to dilate stenoses in the Iliac, Femoral, Popliteal and Renal arteries.

Prescription Use ☒ *(Part 21 CFR 801 Subpart D)* And/ Or Over-The- Counter Use ☐ *(Part 21 CFR 801 Subpart C)*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Donna R. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082646