K102645

2.5 *510(k) Summary*

DEC 10 2010

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

1. General Information

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Summary Preparation Date:	December 8, 2010

2. Device Information

Device Trade Names:	WILLOW PTA Balloon Dilatation Catheter ELM PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Dilatation Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code: LIT)

3. Predicate Devices

WILLOW PTA Balloon Dilatation Catheter predicate

Device Name:	AMPHIRION DEEP 0.0 14"OTW PTA Balloon Dilatation Catheter
510(k) Clearance Number:	K050073, K052791, K042624, K083919

ELM PTA Balloon Dilatation Catheter predicate

Device Name:	Vaccess™ PTA Balloon Dilatation Catheter
510(k) Clearance Number:	K073472

4. Device Description

Both the WILLOW and ELM are co-axial PTA Balloon Dilatation Catheters with a distal inflatable balloon. The lumen between the inner shaft and outer shaft is used for inflation of the balloon with contrast medium; the inner shaft 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 dilating section of the balloon and aid in the balloon placement. The marker bands also indicate the nominal length of the balloon. The catheter tip is designed to ease entry into the peripheral arteries and to facilitate the crossing of tight stenoses.

The following materials are used in the WILLOW PTA Balloon Dilatation Catheter: Nylon 11, Polyethylene, Polycarbonate, and 90% Platinum/10% Iridium. The following materials are used in the ELM PTA Balloon Dilatation Catheter: Nylon 11, Pebax, Polycarbonate, Polyethylene, and 90% Platinum/10% Iridium. All materials in both devices were tested per ISO 10993-1 and determined to be biocompatible.

5. Indications for Use

The WILLOW 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.

The ELM PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

6. Substantial Equivalence

This Premarket Notification aims to demonstrate substantial equivalence of the WILLOW PTA Balloon Dilatation Catheter through comparison with the predicate device – the Invatec AMPHIRION DEEP. The substantial equivalence discussion is demonstrated for the intended use of the WILLOW. Where substantial equivalence is not directly demonstrated from the perspective of technology and performance, design verification testing provides evidence of the substantial equivalance of the WILLOW.

The WILLOW has the same technological characteristics as the AMPHIRION DEEP predicate device in that they are both co-axial catheters with a distal, inflatable balloon. They have similar design, however, the exact specifications of the WILLOW and the AMPHIRION DEEP differ in certain aspects. The differences include a longer inflated balloon length for the WILLOW, higher rated burst pressure for the WILLOW, lower nominal pressure for the WILLOW, different strain relief between the WILLOW and the predicate in terms of design and materials, and different marker bands in terms of materials. In each case that there was a difference between the WILLOW and the predicate device, design verification testing was performed to demonstrate substantial equivalence. In all cases, performance testing demonstrated that the device performed as intended and in compliance with relevant consensus standards.

The Premarket Notification also aims to demonstrate substantial equivalence of the ELM PTA Balloon Dilatation Catheter through comparison with the predicate device – the Bard Vaccess™. Substantial equivalence is demonstrated for the intended use of the ELM device. Where substantial equivalence is not directly demonstrated from the perspective of technology and performance, design verification testing provides evidence of the substantial equivalance of the ELM device.

The ELM device has the same technological characteristics as the Vaccess predicate device in that they are both co-axial lumen catheters with a distal, inflatable balloon. They have similar design, however, the exact specifications of ELM and the Vaccess devices differ in certain aspects. The differences include different strain relief, inner shaft and balloon design between the ELM and the predicate in terms of design and materials, different marker bands in terms of materials, different sheath break sizes compared to the predicate, higher rated burst pressure for the ELM across the product matrix compared with the predicate, higher nominal pressure for the ELM, smaller inflated balloon diameter for the ELM, and the usable catheter length varies slightly compared to the predicate device. In each case that there was a difference between the ELM and the predicate device, design verification testing was performed to demonstrate substantial equivalence. In all cases, performance testing demonstrated that the device performed as intended and in compliance with relevant consensus standards.

7. **Performance Data**

The safety and effectiveness of the WILLOW and ELM PTA Balloon Dilatation Catheters has been demonstrated through data collected from non-clinical design verification/ validation tests and analyses.

Performance testing included generation of compliance data relating balloon diameter to applied pressure to vessel size, sterilization validation, and validation of shelf life. Additionally, the following verification/validation testing was performed: rated burst pressure, multiple inflation/fatigue and leak tight, balloon lengths and marker band position, inflation and deflation time, wire compatibility, catheter effective length, tensile strength, device profile/sheath compatibility, tip profile, radiopacity, simulated use including pushabiity and trackability and sheath compatibility, and manifold testing.

8. **Conclusions**

The substantial equivalence of the ELM and WILLOW PTA Balloon Dilatation Catheters has been demonstrated through comparison with the identified predicate devices. Substantial equivalence is demonstrated for the intended use of both devices. Where substantial equivalence is not directly demonstrated from the perspective of technology and performance, design verification testing provides evidence of the substantial equivalance of the ELM and WILLOW devices. Design verification testing of the WILLOW and ELM meet pre-determined performance characteristics as documented in the Design Output and Product Specification documents. Design validation has been carried out to demonstrate that the WILLOW and ELM designs conform to defined user needs and intended uses as defined in the WILLOW and ELM Design Input and Market Specifications documention.

Additional testing was done to support substantial equivalence to the identified predicate devices. For the WILLOW, rated burst pressure was tested and data demonstrates with 95% confidence that 99.9% of the product meet the rated burst pressure specification and therefore is substantially equivalent to the predicate device. Compliance testing was performed which demonstrated that with 95% confidence that 99.7% of the product meets the compliance specification and therefore satisfies is substantially equivalent to the predicate device.

For the ELM, rated burst pressure was tested and data demonstrates with 95% confidence that 99.9% of the product meet the rated burst pressure specification and therefore is substantially equivalent to the predicate device. Compliance testing was performed which demonstrated that with 95% confidence that 99.7% of the product meets the compliance specification and therefore satisfies is substantially equivalent to the predicate device.

Therefore, the WILLOW and ELM PTA Balloon Dilation Catheters perform as intended and are substantially equivalent with the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Creagh Medical Ltd.
C/O Maureen O'Connell
President
5 Timber Lane
North Reading, MA 01864

DEC 10 2010

Re: K102645
Trade/Device Name: WILLOW PTA Balloon Dilatation Catheter
ELM PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: September 13, 2010
Received: September 13, 2010

Dear Ms. O'Connell:

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 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,

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

Enclosure

2.4(a) *Indications for Use*

510(k) Number: K102645

Device Name: WILLOW PTA Balloon Dilatation Catheter

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Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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2.4(b) *Indications for Use*

510(k) Number: K102645

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Device Name: ELM PTA Balloon Dilatation Catheter

The ELM PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary 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)

Donna R. Vo Mmen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102645

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