JUN 2 9 2012

Submitted by:
Oscor Inc.
3816 De Soto Blvd.
Palm Harbor, FL. 34683

June 29, 2012

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of 21 CFR, Part 807.92.

The assigned 510(k) number is **K120459.**

1. Contact Person:

Ms. Mila Doskocil
Vice President of Regulatory Affairs & Quality Assurance
Oscor Inc.
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Phone: (727) 937-2511
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2. Device Name and Classification

- Trade Name: Adelante® Destino
- Common/Usual Name: Steerable Guiding Sheath
- Classification Name: Introducer, Catheter
- Device Class : Class II
- Regulation Number: 21 CFR 870.1340
- Classification Panel : Cardiovascular
- Product Code: DYB

3. Substantial Equivalence

The Adelante® Destino is substantially equivalent to the following predicate devices:

1) Oscor - Delivery Sheath, Model Adelante Breezeway 510k #K101497
2) St. Jude Medical - Agilis NxT Steerable Introducer 510k #K081645
3) Medtronic – FlexCath Steerable Sheath 510k #K102176

4. Device Description

The steerable guiding sheath, model Adelante® Destino, is designed to assist with the introduction of intravascular devices into the heart using a steerable feature to provide better maneuverability and easier access to hard-to-reach places in the heart. On the steerable handle there is a side port for aspiration and flushing. The guiding sheath comprises of: shaft, steerable handle and side port. The dilator is included with each sheath.

5. Intended Use of the Device

The steerable guiding sheath, model Adelante® Destino, is intended to facilitate the intracardiac placement of diagnostic and therapeutic devices.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices

The Adelante® Destino Steerable Guiding Sheath has similar technological characteristics as the predicate devices mentioned above. They are similar in materials, function, and intended use. The difference from predicate devices is in the incorporation of a steerable handle to deflect the distal end of the sheath and the reinforcement of the tip using multiple biocompatible materials.

7. Tests and Conclusions

Functional and performance testing was conducted to assess the safety and effectiveness of the Adelante® Destino. See table below.

Test Name/ Description	Acceptance Criteria	Pass /Fail
Sheath visual and dimensional test	Visual and dimensional specifications and requirements for the Destino sheath must be met.	Pass
Pull test of sections test	Joints must withstand a pull force of15 N or 3.37 lbf.	Pass
Sheath hub bond test	Sheath to hub joint must withstand a pull force of 15 N or 3.37 lbf.	Pass
Freedom from air leakage test	Sheath must not leak prior to and after the insertion of the dilator and a catheter/device.	Pass
Kink and roll test	The device should be free of any kinks and bends (before and after dilator removal). The sheath body sections must be smooth, properly bonded, and free from damages after the roll test.	Pass
Deflection and handle test	Assembled sheath should deflect 180 degrees in one direction and 90 degrees in the other direction. Sheath should move less than 20 degrees total after introducing test piece ten times. Lock should not break or the handle should not separate throughout the entire test.	Pass
Sheath thermal shock test	After testing, there shall be no discoloration, broken/frayed tubing, cracked split caps, or any other constructional defects or signs of degradation due to testing.	Pass
Dilator visual and dimensional test	Visual and dimensional specifications and requirements for the Destino dilator must be met	Pass
Sheath and dilator fit, functionality, and transition test	The hubs shall have a female 6% (Luer) taper conical fitting for syringes. The sheath must allow the insertion of a 8F (maximum) device. The dilator must be able to snap/lock into the sheath hub. There must be a smooth tapered transition between the sheath and dilator tips. The tips must have a radius free from sharp edges or damages. Any gap between the dilator and sheath must be less than 1 mm.	Pass
Device insertion and withdrawal test	The sheath/dilator tips, as well as the device, must be without damages after the Seldinger method.	Pass
Dilator thermal shock test	After testing, there shall be no discoloration, broken/frayed tubing, cracked split caps, or any other constructional defects or signs of degradation due to testing.	Pass
EtO residual levels testing	EtO residuals must be within limits	Pass
Bioburden testing	Bioburden levels must be within limits	Pass
Endotoxins testing	Endotoxins (LAL) levels must be within limits	Pass
Product sterility testing	Product must remain sterile	Pass

The following tests were performed on the Oscor predicate device, Adelante Breezeway, and adopted to the Adelante Destino:

- Dilator to transseptal needle and guidewire visual and dimensional test
- Dilator body to hub bond test
- Sheath side port holes flush test
- Radio-detectability test

8. Conclusion:

The test data results support the determination of substantial equivalency to predicate devices and it can be concluded that the device is safe and effective for its Intended Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2012

Oscor, Inc.
c/o Ms. Mila Doskocil
Vice President of Regulatory Affairs and Quality Assurance/Compliance
3816 De Soto Blvd.
Palm Harbor, FL 34683

Re: K120459
Trade Name: Adelante Destino
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: June 18, 2012
Received: June 19, 2012

Dear Ms. Doskocil:

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" (21 CFR 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. G. Hillebrenner

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

Enclosures

Attachment 2

Indications for Use Statement

510k Number (if known) – K120459

Device Name: **Steerable Guiding Sheath, model Adelante Destino**

The steerable guiding sheath, model **Adelante Destino** is intended to facilitate the intracardiac placement of diagnostic and therapeutic devices.

Prescription Use _X_ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(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 K120459