# 510(k) Summary

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

OCT 2 0 2010

October 12, 2010

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 **K101497.**

**1. Contact Person:**

Ms. Mila Doskocil
Vice President of Regulatory Affairs & Quality Assurance
Oscor Inc.
3816 De Soto Blvd.
Palm Harbor, Fl. 34683
Phone: (727) 937-2511
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**2. Device Name and Classification**

- Trade Name: Adelante® Breezeway
- Common/Usual Name: Delivery 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® Breezeway is substantially equivalent to the following predicate devices:

1) Oscor Inc., Adelante® Sigma, Sigma AT and Targa, K090114
2) Boston Scientific, Convoy Advanced Delivery Sheath Kit, K072719
3) Thomas Medical, Reinforced Catheter Introducer system, K081341
4) Biosense Webster Inc., Preface Guiding Sheath, K001139
5) St. Jude Medical, Fast-Cath Hemostasis and Transseptal Introducer, K061015

**4. Device Description**

The Adelante® Breezeway Delivery Sheath is designed to facilitate the introduction of catheters to any of the heart chambers, including the left atrium via a transseptal puncture. This introducer delivery sheath consists of a braided sheath with a side port with a three-way stopcock, hemostatic valve, and a dilator.

The distal tip of the sheath has side flush portholes. The dilator can be locked on to the hub of the sheath. The sheath is supplied in 10 F and two overall lengths, 63 cm and 81 cm, and dilator is supplied in two overall lengths, 68 cm and 86 cm. The dilator profile curves are 55, 70, 90, 120 degrees. There are no accessories supplied with this device.

**5. Intended Use of the Device**

The Adelante® Breezeway Delivery Sheath 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® Breezeway Delivery Sheath has similar technological characteristics as the predicate devices. They are similar in materials, function, and intended use.

**7. Tests and Conclusions**
Functional and performance testing was conducted to assess the safety and effectiveness of the Adelante® Breezeway. See table below.

| Test Name/ Description | Acceptance Criteria | Pass /Fail |
|---|---|---|
| Sheath visual and dimensional tests (includes curve verification) | Specific visual and dimensional specifications | Pass |
| Dilator visual and dimensional tests (includes curve verification) | Specific visual and dimensional specifications | Pass |
| Dilator to TS needle and Guidewire visual and dimensional tests | Free and smooth insertions and other insertion/transition requirements | Pass |
| Sheath joints bonding tests | All joints must withstand a designated pull force | Pass |
| Dilator body to hub bond test | Hub bond to dilator tube must withstand a designated pull force | Pass |
| Sheath and Dilator fit, functionality, and transition tests | Compatibility with Luer fitting, compatibility with 10 F device, dilator to sheath fit must be within specifications | Pass |
| Air leakage testing | The sheath must not leak prior to and after the insertion of a dilator and a catheter/device | Pass |
| Sheath side port holes flush test | The sheath must be capable of aspiration/flushing with and without inserted dilator/device. | Pass |
| Torque response test | Minimum 1:1 torqueability<br>Pre-determined torque force | Pass |
| Insertion and withdrawal of dilator into sheath hemostatic valve test | Insertion and withdrawal force must be within specifications | Pass |
| Device insertion and withdrawal test | No damage when using the Seldinger method | Pass |
| Kink and Roll tests | Free of kinks and bends | Pass |
| Radio-detectability test | Device must be radio-detectable and visible under fluoroscopy | Pass |
| Exposure to Ethylene Oxide sterilization and Thermal shock | Device must be physically and functionally unaffected by EtO and thermal shock exposure | Pass |
| Testing of EtO residual levels | EtO residuals must be within limits | Pass |
| Product sterility testing | Product must remain sterile | Pass |
| Bioburden testing | Bioburden levels must be within limits | Pass |
| Endotoxins testing | Endotoxins (LAL) levels must be within limits | Pass |

As required by the risk analysis performed for the Adelante® Breezeway, the designated individual(s) performed all verification and validation activities and the results of the activities demonstrated that the predetermined acceptance criteria were met. Oscor Inc. is in conformance with the design control requirements as specified in 21 CFR, Part 820.30.

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

Oscor Inc.
Mila Doskocil
Director of Regulatory Affairs/Compliance
3816 De Soto Boulevard
Palm Harbor, FL 34683

OCT 20 2010

Re: K101497
Trade/Device Name: Adelante Breezeway Delivery Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 1, 2010
Received: October 4, 2010

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" (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

# Indications for Use

OCT 2 0 2010

510(k) Number (if known): K101497

Device Name: Adelante Breezeway Delivery Sheath

Indications For Use: The Adelante Breezeway Delivery Sheath is intended to facilitate the intracardiac placement of diagnostic and therapeutic devices.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101497