510(k) SUMMARY

DEC 1 3 2012

Device Name

Device Trade name	Common/classification name
Delivery Sheath, Model Adelante® Breezeway	Introducer, Catheter

Address and Registration #

Manufacturer	Sterilization Site
Oscor Inc. 3816 De Soto Boulevard Palm Harbor, FL 34683	1. International Sterilization Laboratory Inc. (ISL) 217 Sampey Road, Groveland, FL 34736 2. Oscor DMB Sterilizer 3816 De Soto Boulevard, Palm Harbor, FL 34683 3. Oscor Caribe, LLC Avenida Las Americas, Nave I-2 Santo Domingo, Dom. Republic

Contact

Mila Doskocil V.P. of Regulatory Affairs & Quality Assurance	mdoskocil@oscor.com 727-937-2511

FDA Registration #	FDA Registration #
1035166	1061927 (ISL) 1035166 3004785273

Device Class Introducers, catheters, are classified as Class II, Reg No. 870.1340, code DYB

Type of 510k Traditional

Reason for 510k Addition of indications into the Indications for Use statement.

Predicate Device Information Thomas Medical; Reinforced Catheter Introducer system, K081341

Terumo Medical Corp., Destination Guiding Sheath, K081045

Arrow (sub. Teleflex), Arrow-Flex Sheath Introducer Set, K970229

Labeling and Indications for Use	Proposed IFU only with modified Indications for Use statement is attached. **Previously cleared Indications for Use** The Adelante® Breezeway Delivery Sheath is intended to facilitate the intracardiac placement of diagnostic and therapeutic devices. **Proposed Indications for Use:** The Adelante® Breezeway Delivery Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements. Do not use this device for neural placements. The **Indications for Use** statement is attached.
Device Description, Modification and Comparison to Predicate devices	**This is a modification to Indications for Use statement only. There was no change in the text of IFU and method of use.** There is no modification to the device itself. The Adelante® Breezeway Delivery Sheath has been cleared in K101497 and will remain intact, and no modifications to product labels. **Modification of Indications for Use statement** was in the addition of indications for placement into vasculature and renal arteries, but restricted to peripheral placements only and excluding neural placements. The reason for modification is explained in the **Rationale and Evaluation document** attached. The use of Breezeway delivery sheath has been **compared to the predicate devices** and found comparable to: Thomas Medical Intended Use (see the attached information in section Predicate Devices): The "Reinforced Catheter Introducer" is indicated for use in arterial and venous procedures requiring percutaneous introduction of therapeutic or diagnostic intravascular devices. Terumo, Intended Use (see the attached information in section Predicate Devices): "Destination" is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity, renal arteries, and carotid arteries.

Modification Statement	This labeling modification has not altered the fundamental technology and the intended use methods from the predicate devices.
Substantial Equivalence	The additional indications for Adelante® Breezeway Delivery Sheath described in this submission are, in our opinion, substantially equivalent to the predicate devices and other similar introducer/guiding sheaths in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mila Doskocil
Vice President of Regulatory Affairs & Quality Assurance
Oscor Inc.
3816 De Soto Boulevard
Palm Harbor, FL 34683

DEC 1 3 2012

Re: K122958
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: September 21, 2012
Received: September 25, 2012

Dear Mila 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 Statement

510k Number (if known) – K122958

Device Name: **Adelante® Breezeway Delivery Sheath**

The Adelante® Breezeway Delivery Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements.
Do not use this device for neural placements.

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 K122958