



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

September 22, 2015

Jan Flegeau
Director of Regulatory Affairs
Oscor Inc.
3816 DeSoto Blvd
Palm Harbor, FL 34683

Re: K151951

Trade/Device Name: Destino Reach, Steerable Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 14, 2015
Received: Aug 24, 2015

Dear Mr. Flegeau:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

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) K151951

Device Name: **Steerable Guiding Sheath, Destino Reach**

The steerable guiding sheath, Destino Reach 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)

510(k) SUMMARY

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Oscor Inc. is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number K151951

DATE: Septembre 21, 2015

APPLICANT: **OSCOR INC.**
3816 De Soto Boulevard
Palm Harbor, Florida 34683

CONTACT PERSON: Jan Flégeau
Director of Regulatory Affairs
Phone: 727-937-2511
Fax: 727-934-9835
E-mail: jflegeau@oscor.com

TRADE/DEVICE NAME: Destino Reach, Steerable Guiding Sheath

DEVICE CLASSIFICATION NAME: Introducer, catheter

REGULATORY CLASSIFICATION: II

REGULATION NUMBER: 870.1340

PRODUCT CODE: DYB

REVIEW ADVISORY COMMITTEE: Cardiovascular

MANUFACTURED BY: Oscor Inc.

Sites	Activity	FDA Establishment Registration
3816 De Soto Boulevard Palm Harbor, Florida 34683	Design, development, manufacture	1035166
4875 Palm Harbor Blvd. Palm Harbor FL 34683	Design, development, manufacture, sterilization	3010274750
1053 Progress Court Palm Harbor FL 34683	Final pack and Labeling	3010938037

STERILIZATION SITES:

1. International Sterilization Laboratory Inc. (ISL)
217 Sampey Road
Groveland, FL 34736

Or

2. Oscor DMB Sterilizer
3816 De Soto Boulevard
Palm Harbor, Florida 34683

INTENDED USE:

The Destino Reach, steerable guiding 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.

DEVICE DESCRIPTION

The Destino Reach Steerable Guiding Sheath is a percutaneous steerable sheath designed to facilitate the intracardiac, renal and peripheral placement of diagnostic and therapeutic devices. The device features an adjustable tip through use of a rotating collar that allows the physician to perform a bi-deflection at the distal tip section of the sheath. The sheath has a hemostatic valve, sideport with stopcock, radiopaque distal tip, contains side flush portholes and is deflectable by rotating the collar incorporated into the handle. The dilator has depth markings and locks onto the sheath. The dilator has a tapered distal tip and an inner lumen recommended for use with 0.035" to 0.038" guidewire and/or transseptal needle.

REASON FOR PREMARKET NOTIFICATION:

New device submission seeking 510(k) clearance for the Destino Reach, steerable guiding sheath.

PREDICATE DEVICES 510(k) # and DESCRIPTION

Adelante Destino, steerable guiding sheath K120459 (original submission) and K122960 (modified intended use)

Destino Twist, steerable guiding sheath K140406

MODIFICATION TO PREDICATE DEVICES

The rotating collar/twisting mechanism in the handle of the Destino Twist (K140406) was added to the Adelante Destino (K120459 and K122960) to create the proposed device Destino Reach.

Rationale for these changes: physician preference/customer demand for a bi-directional tip deflection steerable guiding sheath with a rotating collar twisting mechanism instead of a deflection lever.

Intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.

DEVICE PERFORMANCE

Standards followed include:
BS EN ISO 14971:2012, Medical devices
Application of risk management to medical devices

AAMI/ANSI/ISO 11135: 2014, Sterilization of health-care products Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

AAMI/ANSI/ISO 10993-7:2008, Cor. 2009, Biological evaluation of medical devices, Part 7, Ethylene oxide sterilization residuals

ISO 10555-1 2013, Intravascular catheters- Sterile and single use catheters, Part 1, General requirements. (Requirements for flow rate and power injections not followed as this does not apply to an introducer.)

ISO 11070: 1998, Sterile single-use intravascular catheter introducers. (Requirements for needles do not apply since the product is not packaged with a needle).

TESTING:

Oscor Inc. conducted verification and validation testing including functional system testing, risk analysis, biocompatibility and packaging/transportation qualification. Based on this testing, we have determined that the device performs as well as the legally marketed predicate devices identified in this summary.

CONFIDENTIALITY STATEMENT:

Oscor Inc. considers this 510(k) notification as confidential commercial information. Oscor Inc. has taken precautions to protect the existence of this submission. To the best of our knowledge, neither Oscor nor any other party has disclosed information concerning this submission through advertisements of any other manner. There have been no prior submissions for the subject device.

SUBSTANTIAL EQUIVALENCE:

Oscor Inc. considers the Destino Reach as substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Adelante Destino K120459 (original submission) and K122960 (modified intended use) and the Destino Twist, steerable guiding sheath K140406.