June 3, 2021

Oscor, Inc.
Doug Myers
VP of QA and RA
3816 DeSoto Boulevard
Palm Harbor, Florida 34683

Re: K210627
Trade/Device Name: Breezeway II
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 4, 2021
Received: May 5, 2021

Dear Doug Myers:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Finn Donaldson
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210627

Device Name
Breezeway II

Indications for Use *(Describe)*
The Breezeway II products are 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Submission Sponsor

Oscor Inc.

Address: 3816 DeSoto Boulevard

Palm Harbor, Florida 34683

USA

Phone: 727-937-2511

Fax: 737-934-9835

Contact: Doug Myers, VP or QA and RA

2. Date Prepared

April 19, 2021

3. Device Identification

Trade/Proprietary Name:	Breezeway II
Common/Usual Name:	Delivery Sheath
Classification Name:	Catheter Introducer
Classification Regulation:	870.1340
Product Code:	DYB
Device Class	Class II
Classification Panel:	Cardiovascular

4. Legally Marketed Predicate Device

K122958 Delivery Sheath, Model Adelante Breezeway

5. Device Description

The Breezeway II Delivery Sheath consists of a braided sheath with a side port with a three-way stopcock, hemostatic valve, and dilator. The Breezeway II Plus models include these same components plus a loader accessory. The distal tip of the sheath is radiopaque and contains side flush portholes. The dilator can be locked on to the hub of the sheath.

The Adelante Breezeway Delivery Sheath (K122958) is modified with the following changes, to be marketed as the Breezeway II and Breezeway II Plus Delivery Sheath:

- Addition of French sizes (9F, 11F, 12F, and 14F).
- Extending the usable length to 110 cm (for 6F to 10F sizes).
- Sheath Hub for new French sizes (9F to 14 F) designed to incorporate larger French sizes.
- Dilator hub design features a screw on design for the 6F, 7F, and 8F sizes, and an oval shaped hub with lock for 9F to 14 F sizes.
- Dilator material for 14F size is LDPE for the body, and HDLE for the hub, no material changes to other sizes.
- Addition of a loader accessory component as an added option to facilitate the insertion of devices through the sheath's hemostatic valve (Breezeway II Plus only)

6. Indications for Use Statement

The Breezeway II products are 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.

7. Substantial Equivalence Discussion

The following table compares Breezeway II products to the predicate device with respect to intended use, technological characteristics and principles of operations, providing more detailed information regarding the bases for the determination of substantial equivalence.

Table 7A. Comparison of the technological characteristics of Breezeway II to predicate device.

Comparator	New Device	Predicate Device
Device Name	Breezeway II Delivery Sheath and OEM Branding (ODS III)	Adelante Breezeway Delivery Sheath
Regulatory Decision	This submission	K122958
Product Code	DYB	Same as Breezeway II
Regulation Number	870.1340	Same as Breezeway II
Regulation Name	Introducer, Catheter	Same as Breezeway II
Intended Use	To facilitate the intracardiac placement of diagnostic and therapeutic devices	Same as Breezeway II
Device Placement/ Introduction	Intracardiac, renal, or other placements, not for neural placement	Same as Breezeway II
Environmental Use	Hospital	Same as Breezeway II
Intended User	Cardiologist, Electrophysiologist Surgeon, Neurovascular Surgeons	Same as Breezeway II
Single Use	Yes	Same as Breezeway II
Tissue Contact	Yes	Same as Breezeway II
Labeling	Sterile, Single Use, Prescription	Same as Breezeway II

Comparator	New Device	Predicate Device
French Size	6F to 14 F	6F to 10F
Usable Length	79 cm (6F to 14 F) 110 cm (6F to 10F)	68 to 86 cm
Distal Tip Fixed Curve	45°, 180°	55°, 70°, 90°, 120°
Sheath Hub Design	Breezeway II small hub (6F to 8F) Breezeway II large hub (9F to 14F)	Breezeway Sigma Hub
Sheath Hub Cap	Small cap, a screw-in feature (6F to 8F) Large cap (9F to 14F)	Sigma Cap
Sheath Hub Cap Material	Polycarbonate	Same as Breezeway II
Hemostatic Valve Material	Silicone	Same as Breezeway II
Sheath side port with 3-Way Stopcock	Yes	Same as Breezeway II
Shaft Construction	Multilayer Braided Shaft	Same as Breezeway II
Sheath Materials (Inner and Outer Diameter)	Liner (Inner): PA12 Distal Tip (Outer): Pebax 45D Proximal Shaft (Outer): Pebax 63D	Same as Breezeway II
Sheath Coating	Hydrophobic	Same as Breezeway II
Sheath Flush Side Hole	Yes	Same as Breezeway II
Marker Band	Gold	Same as Breezeway II
Dilator Hub Design	Screw-in (6F to 8F) Oval Shape with Hub Lock (9F to 14F)	Oval Shape
Dilator Material	6F to 12F: HDPE (Body and Hub) 14F: LDPE (Body), HDPE (Hub)	HDPE (Body and Hub)
Dilator Length	85 cm to 115 cm	68 cm and 86 cm
Max. Compatible Guidewire	0.038”	Same as Breezeway II
Loader	Included for Breezeway II Plus Delivery Sheath and ODS III models	None
Packaging Materials	Solid Bleached Sulfate (SBS) cardboard, Single Chevron pouch and SBS cardboard product box	Same as Breezeway II
Sterilization	Ethylene Oxide	Same as Breezeway II
Shelf Life	3 years	Same as Breezeway II
Kit Components	Breezeway II Delivery Sheath: Sheath, Dilator, IFU Breezeway II Plus Delivery Sheath: Sheath Dilator, Loader, IFU	Sheath, Dilator, IFU

8. Biocompatibility Data

The materials, construction and intended use of Breezeway II Delivery Sheath devices are comparable to the predicate device. The biological safety of the catheter introducer was evaluated in accordance with ISO 10993-1:2009. Under these, for the stated indications for use the device was classified as (A) limited exposure external communicating device, contacting circulating blood. The results for the biocompatible testing of the catheter introducer for, cytotoxicity, sensitization, irritation: intracutaneous toxicity, system toxicity (acute systemic injection and pyrogencity (material mediated pyrogen), and hemocompatibility

(hemolysis, complement activation, in-vivo thrombogenicity) demonstrated no negative impacts from the materials that are used in Breezeway II. The catheter introducer materials in direct tissues contact include Pebax, Silicone, Polycarbonate, Pellethane, PA, and HDPE. Breezeway II Delivery Sheath products met the biological safety and compatibility requirements of ISO 10993-1: 2009.

9. Non-Clinical Performance Data

A summary of the bench performance testing for design verification of Breezeway II Delivery Sheath products has demonstrated that the product, as designed, meets Oscor Inc. design input requirements and conforms to ISO 11070:2014, sterile single-use intravascular introducers, dilator and guidewire. Performance testing is presented in summary detailing the well-established testing protocols, acceptance criteria, details of deviations, expected results and actual results. The basis for a determination of substantial equivalence of the device is demonstrated by the following:

- Tensile Force: All tested devices met the test acceptance criteria, minimum 15N between critical joints (Sheath Section, Sheath Shaft to Sheath Hub, Dilator Hub, Accessory Tool Hub, Side Port Arm Tube to Sheath Hub and Stopcock Valve, and Sideport Arm Tube to Loader Proximal Hub and Stopcock), per ISO 11070:2014.
- Liquid Leakage: All tested devices met the test acceptance criteria, no fluid leakage from critical joints (Hemostasis Valve, or under pressure), per ISO 11070:2014.
- Device Compatibility: All tested device met the test acceptance criteria, compatible dimensions (Introducer Sheaths with Dilators, Dilator with Transseptal Needle, Dilator and Guidewire, and Accessory Tool with Sheath Introducer), per Oscor Inc. design requirement.
- Device Functionality and Transition: All tested devices met the test acceptance criteria, no gap or damage following insertion (Sheath with Dilator, and Accessory Tool with Sheath Introducer), per Oscor design requirement.
- Flushing and Aspiration: All tested devices met the test acceptance criteria, capable of aspiration without obstruction or ingress of air through susceptible areas (Sheath Introducer, and Accessory Tool), per ISO 11070:2014.
- Introducer Sheath Kink Resistance: All tested devices met the test acceptance criteria, capable of bending 180°, per Oscor design requirement.
- Sheath Introducer Torque: All test devices met the test acceptance criteria, free of exposed braid at 180° and 360° rotation, per Oscor design requirement.
- Radio-detectability: All test devices (Sheath and Dilator) met the test acceptance criteria of visibility and identification under fluoroscopy, per Oscor design requirement.

Each test demonstrated that Breezeway II Delivery Sheaths meets the standard and the design requirement, making it substantially equivalent to the predicate device. As designed and tested, the differences between Breezeway II Delivery Sheaths and the predicate device do not raise new or different questions about safety or effectiveness that have not been mitigated as far as possible through design and verification testing.

10. Clinical Performance Data

There was no clinical testing required to support the medical device.

11. Statement of Substantial Equivalence

Breezeway II Delivery Sheath products have the same intended use as the legally marketed predicate device. Performance testing verified that Breezeway II Delivery Sheath products comply with all applicable voluntary standards such as ISO 10993-7, ISO 11135, ISO 11737, ISO 11607, ISO 10993-1, ISO 10993-5, ISO10993-10, ISO 10993-11, ISO 10993-4 and ISO 14971. Breezeway II Delivery Sheath products also meets design requirements where no applicable standard could be used. This includes ISO 11070:2014. There was no recognized performance standards for this device.

It has been shown in this Premarket Notification Submission that the differences between Breezeway II Delivery Sheath products and the legally marketed predicate device do not raise any questions regarding safety and effectiveness. Breezeway II Delivery Sheath products, as designed and manufactured, are determined to be substantially equivalent to the referenced legally marketed predicate device.