May 23, 2022

Onocor Vascular LLC
Tiffini Wittwer
Regulatory Affairs
808 General Sterling Drive
West Chester, Pennsylvania 19382

Re: K212988
Trade/Device Name: ONO Retrieval Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: April 14, 2022
Received: April 19, 2022

Dear Tiffini Wittwer:

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,

Gregory O'Connell
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)*
K212988

Device Name
ONO Retrieval Device

Indications for Use *(Describe)*
The Onocor ONO Retrieval device is indicated for use in the cardiovascular system to retrieve objects using minimally invasive surgical procedures. Procedures include retrieval of intravascular foreign objects such as coils, balloons, catheters, guidewires and/or filters within the cardiovascular system. This device is not intended for use in the coronary arteries or neurovasculature.

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

K212988

Date Prepared:	May 20, 2022
Company:	Onocor LLC 808 General Sterling Drive West Chester, PA 19382
Contact:	Tiffini Wittwer Regulatory Affairs Phone: 707-799-6732 Email: twittwer@mededge.io
Device Trade Name:	ONO Retrieval Device
Device Common Name:	Percutaneous Retrieval Device
Device Classification:	Device, Percutaneous Retrieval Product Code: MMX 21 CFR 870.5150 Class II Review Panel: Cardiovascular Devices
Predicate Device:	K170987 Avantec Vascular Corporation Captus Vascular Retrieval System
Description of the Device:	The ONO Retrieval device is constructed of 12 Fr stainless steel reinforced catheter, a series of braided nitinol loops forming a basket, a peel away sheath, inner catheter and stop-cocks. The peel away sheath is advanced to compress the nitinol basket for introduction and then removed. The ONO is compatible with up to a 7 Fr manipulation device or snare and with 12Fr to 26 Fr retrieval sheaths. The ONO has a working length of 86 cm.
Indication for Use:	The ONO retrieval device is intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including, but not limited to, guidewires, coils balloons, catheters and filters.
Technological Characteristics:	A comparison of the technological characteristics of the subject device and the predicate device shows the ONO Retrieval device to be substantially equivalent to the current marketed predicate device. Equivalence is based upon the product performance, design, and intended use. The ONO Retrieval device and the predicate devices have

similar materials of construction, dimensional specifications, designs, and sterilization process.

Performance Tests (Non-Clinical):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices. A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the ONO Retrieval device substantial equivalence.

Performance Testing, including:

- Dimensional Testing
- Tensile Strength
- Corrosion Resistance
- Catheter Kink Testing
- Torque Strength
- Simulated Use
- Radiopacity
- Design Validation Testing and Summative Usability Testing
- Distribution Testing
- Fatigue

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material Mediated Pyrogenicity (ISO 10993-11)
- Hemolysis (ISO 10993-4)
- Thrombogenicity (ISO 10993-4)
- Complement Activation (ISO 10993-4)

A pre-clinical study was performed in a porcine model comparing the subject and predicate devices. Retrieval of various foreign objects from the vascular system was performed to demonstrate that the device is appropriate with the stated indications.

Furthermore, histology of the surface tissue interaction and thrombogenicity were assessed and compared to the predicate.

Substantial Equivalence: Based on the Indication for Use, design, safety and performance testing, the ONO Retrieval device met the requirements for its intended use and are substantially equivalent to the predicate device.

Conclusion: The result of all testing demonstrates that the ONO Retrieval device is substantially equivalent to the predicate device.