June 27, 2024

Eximo Medical, Ltd.
Kasey Newcomb
Manager, Regulatory Affairs
AngioDynamics, Inc
603 Queensbury Ave
Queensbury, New York 12804

Re: K241553
Trade/Device Name: Auryon Atherectomy Catheter 1.7mm; Auryon Atherectomy Catheter 1.7mm, Hydrophilic Coating
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 31, 2024
Received: May 31, 2024

Dear Kasey Newcomb:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.06.27 15:37:25 -04'00'

For

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241553

Device Name

Auryon Atherectomy Catheter 1.7mm;
Auryon Atherectomy Catheter 1.7mm, Hydrophilic Coating

Indications for Use *(Describe)*

The Auryon™ Atherectomy System and Auryon Atherectomy Catheters with aspiration are indicated for use as atherectomy devices for arterial stenoses, including in-stent restenosis (ISR), and to aspirate thrombus adjacent to stenoses in native and stented infra-inguinal arteries.

The Auryon™ Atherectomy System and Auryon Atherectomy Catheters without aspiration are indicated for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY FOR THE AURYON ATHERECTOMY SYSTEM

SPONSOR

Eximo Medical Ltd
Pekeris St 3
Rehovot, Israel 7670203

CONTACT

Yoel Zabar
Sr. Director, R&D & Site Manager
Eximo Medical Ltd.
Telephone: 972-8-6307639
Email: yoelz@eximomedical.com

Kasey E Newcomb
Manager, Global Regulatory Affairs
AngioDynamics, Inc
Tel: 508.658.7813
Email: knewcomb@angiodynamics.com

DEVICE NAME

Trade Name:	Auryon Atherectomy Catheter 1.7mm; Auryon Atherectomy Catheter 1.7mm with Hydrophilic Coating
Common/Usual Name:	Peripheral Atherectomy Catheter
Classification Name:	Intraluminal Artery Stripper (21 CFR § 870.4875, Class II, Pro-Code MCW)
Classification Panel:	Cardiovascular

PREDICATE DEVICE

510(k):	K233668
Trade Name:	Auryon™ Atherectomy System
Common/Usual Name:	Peripheral Atherectomy Catheter
Classification Name:	Intraluminal Artery Stripper (21 CFR § 870.4875, Class II, Pro-Code MCW)
Classification Panel:	Cardiovascular

DEVICE DESCRIPTION

The Auryon™ Atherectomy System consists of two sub-units: 1) a single use catheter ("Auryon catheter"); and 2) a laser console. The Auryon catheter is a single use catheter that is made of an array of optic fibers surrounded by a circumferential blunt blade at its distal tip. The Auryon™ catheter is connected to the laser system via its connector and transmits energy at pre-set fluence levels of 50 and 60 mJ/mm2 to the occluded or narrowed artery. The laser delivers very short high intensity pulses which travel from the laser, through the fibers, and emerge from the polished ends of the individual fibers. As the UV light emerges from the fiber end, it will be absorbed by the fluid, and create a cavitation bubble within the fluid. The collapse of this bubble results in a photoacoustic shockwave that disintegrates rigid materials such as calcified lesions without relying on thermal degradation to break down the stenotic material.

The Auryon™ Atherectomy System must work over a commercially available guide wire that crosses the lesion intra-luminally. The catheters are available in seven configurations (0.9mm, 0.9mm XL, 1.5mm, 1.5mm XL, 1.7mm, 2.0mm and 2.35mm), with and without hydrophilic coating.

For the small size catheters (i.e., 0.9mm,1.5mm, and 1.7mm), there is a designated lumen tube for a guidewire at the center of the inner blunt blade. The 0.9mm, 1.5mm, and 1.7mm catheters do not have an aspiration feature and have not been tested in ISR lesions.

The larger Auryon catheters (i.e., 2.0mm and 2.35mm) have an eccentric guidewire lumen and include additional features consisting of an aspiration feature (both catheters) and an "off-center" feature 2.35mm only. The aspiration feature is intended for debris and thrombus collection and removal from the vessel during the atherectomy procedure. These devices are also indicated for treatment of In-Stent Restenosis (ISR) lesions.

The "off-center" feature is included in the 2.35 mm catheter only and is designed to facilitate debulking of lesions in blood vessels beyond the catheter's diameter.

INDICATION FOR USE

The Auryon™ Atherectomy System and Auryon Atherectomy Catheters with aspiration are indicated for use as atherectomy devices for arterial stenoses, including in-stent restenosis (ISR), and to aspirate thrombus adjacent to stenoses in native and stented infra-inguinal arteries.

The Auryon™ Atherectomy System and Auryon Atherectomy Catheters without aspiration are indicated for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions.

COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Auryon Atherectomy System is substantially equivalent to the predicate Auryon Atherectomy K233668. Both laser atherectomy devices have identical laser wavelength (355 nm), laser fluence levels (50 and 60 mJ/mm^2), pulse rate (40Hz), pulse duration (10-25ns), maximum output (33.5mJ) and materials. The difference between the proposed device and predicate device is the addition of a 1.7mm catheter (1.75mm/0.069inch diameter) with a 150cm long working length. The 1.7mm catheter is offered both with and without a hydrophilic coating. The technological characteristic of the proposed device is substantially equivalent with the respect of the system design and function to that of the specified predicate device.

DEVICE MODIFICATIONS AND RISK ASSOCIATED WITH THE DESIGN MODIFICATION(S)

Modifications made to the Auryon Atherectomy System were limited to introducing a 1.7mm Catheter. There is no change to the principles of operations, indications for use, intended purpose, technology characteristics, between the proposed system and the predicate.

The impact of the change as described within this submission were evaluated a part of the Risk analysis activity in terms of new/existing risks and new/existing failure modes. The results of this Risk Analysis activity were compared to the current risk Analysis; the conclusion drawn from this assessment, determined that the additional catheter size did not impact or modify an existing risk nor necessitate a new or modified risk.

COMPARISON OF PERFORMANCE DATA

The new 1.7mm Auryon Atherectomy System Catheter was tested using the same methods and acceptance criteria as the predicate device. Specific tests are listed below:

- Catheter Shaft OD, ID, Working Length
- Guard Tube Length
- Catheter Trackability (Simulated Use)
- Shaft Pull Test
- Inner Blade Pull Test
- Proximal Section Pull Test
- Luer Pull vs Handle Pull Test
- Distal Tip Evaluation
- Optical Functionality Test
- Catheter Torque Strength
- Fatigue Test
- Catheter Optical Durability
- Evaluation of Hydrophilic Coating

STERILIZATION VALIDATION

Both the proposed 1.7mm Auryon Atherectomy System Catheter and the predicate Auryon Atherectomy System Catheters will be sterilized via the same process. Sterilization Validation on the proposed 1.7mm Auryon Atherectomy System Catheter was conducted per the below:

- Bioburden Determination
- LAL Testing

CONCLUSION

Assessment of the similarities and differences of the proposed Auryon Atherectomy System and the predicate Auryon Atherectomy System concludes that the devices are substantially equivalent to one another; specifically:

- The proposed and predicate device have the identical Pro-Code, Regulation Number, Regulation Name, and Regulatory Class;
- The proposed and predicate device have identical Indications for Use;
- The proposed and predicate devices incorporate the identical operating principle, mechanism of action, and are intended for the same patient populations; and,
- With the exception of the newly added catheter size, the proposed and predicate employ an identical overall design, materials of manufacture, performance testing, sizes, and configurations.

The sum of these evaluations and determinations lead Eximo Medical Ltd. to conclude that substantial equivalence has been demonstrated, and that the existing data and additional testing have confirmed that there are no new questions of safety or effectiveness.