December 15, 2023

Eximo Medical, Ltd.
℅ James Welsh
Director, Regulatory Affairs
AngioDynamics, Inc
603 Queensbury Ave
Queensbury, New York 12804

Re: K233668
Trade/Device Name: Auryon™ Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 15, 2023
Received: November 15, 2023

Dear James Welsh:

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.12.15 09:41:19 -05'00'

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)*
K233668

Device Name
Auryon™ Atherectomy System

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.

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510(K) SUMMARY FOR THE EXIMO MEDICAL LTD. AURYON ATHERECTOMY SYSTEM

Date Prepared: December 14, 2023

Sponsor

Eximo Medical Ltd
Pekeris St 3
Rehovot, Israel 7670203

Contact

Yoel Zabar
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Eximo Medical Ltd.
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Subject Device

Trade Name:	Auryon™ Atherectomy System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21CFR870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class 2
Product Code:	MCW
Classification Panel:	Cardiovascular Devices

Predicate Device

510(k) Reference	**K230709**
Trade Name:	Auryon™ Atherectomy System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21CFR870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class 2
Product Code:	MCW
Classification Panel:	Cardiovascular Devices

Purpose

The purpose of this Special 510(k) is to introduce into commercial distribution a modification of the Auryon Atherectomy System previously cleared under predicate 510(k) K230709, specifically:

- addition of new longer size 1.5 mm catheters (225 cm vs the current 150 cm)
- addition of new longer size 0.9 mm catheters (225 cm vs the current 150 cm)
- a slight 0.001” increase in the ID of the 0.9 mm catheter

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/mm^2 to the occluded or narrowed artery.

The Auryon™ Atherectomy System must work over a commercially available 0.014" guide wire that crosses the lesion intra-luminally. The catheters are available in six configurations (0.9mm, 0.9mm XL, 1.5mm, 1.5mm XL, 2.0mm and 2.35mm), with and without hydrophilic coating.

For the small size catheters (i.e., 0.9mm and 1.5mm), there is a designated lumen tube for a guidewire at the center of the inner blunt blade. The 0.9mm and 1.5mm 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.

The modification associated with this submission is to add a second catheter length (225cm) for the size 0.9 and 1.5 mm catheter sizes. The ID of the 0.9mm catheter is also increased slightly.

There are no changes to the Auryon Laser Console unit associated with this submission.

Indications for Use/Intended 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 Similarities and Differences in Technological Characteristics and Performance

As detailed below, the proposed Auryon Atherectomy System is Substantially Equivalent to the predicate device Auryon Atherectomy Catheters.

Device Comparison	Subject Device: Auryon Atherectomy System	Predicate Device: Auryon Atherectomy System (K230709)
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.	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.
Regulation Number	21 CFR §870.4875	21 CFR §870.4875
Regulatory Class	Class II	Class II
Product Code	MCW	MCW
Active Medium	Nd:YAG	Nd:YAG
Laser Wavelength	355 nm	355 nm
Laser Fluence levels	50 and 60 mJ/mm^2	50 and 60 mJ/mm2
Pulse Rate	40 Hz	40 Hz
Pulse Duration	10-25 ns	10-25 ns
Maximum output	33.5 mJ	33.5 mJ
Catheter sizes	0.9mm, 1.5 mm, 2.0mm, 2.35mm, 0.9mm XL, 1.5mm XL	0.9mm, 1.5 mm, 2.0mm, 2.35mm
Platinum/Iridium marker band	Included in 0.9 mm and 0.9mm XL catheters only	Included in 0.9 mm catheter only
Catheter Sterilization Method	Ethylene Oxide	Ethylene Oxide

Comparison of Performance Data

The new 0.9 mm XL and 1.5 mm XL Auryon Atherectomy System devices were tested using the same methods and acceptance criteria as was done in the predicate device 510(k). The specific tests are listed below

Summary of Performance Testing

• Catheter shaft ID, OD, and working length
• Catheter trackability in simulated anatomical shape
• Optical Functionality test
• Catheter torque test
• Catheter optical durability
• Validation that the longer catheters can be sterilized in the predicate device sterilization process
  o B&F testing
  o Bioburden recovery rate
  o Bioburden determination
  o Comparison of natural product resistance to Biological Indicators
  o EO Residuals
  o LAL testing

Substantial Equivalence

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 ProCode, 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 longer catheter length options, 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.