September 26, 2022

Eximo Medical Ltd.
c/o James Welsh
Director, Regulatory Affairs
AngioDynamics
603 Queensbury Ave
Queensburgy, New York 12804

Re: K220116
Trade/Device Name: Auryon Atherectomy Catheters
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: August 30, 2022
Received: August 30, 2022

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 (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)*
K220116

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.

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

Date Prepared: September 22, 2022

Sponsor

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Contact

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Subject Device

510(k) Reference	**K220116**
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	**K202835**
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 510(k) is to introduce into commercial distribution four new catheter item codes for use with the existing Auryon Atherectomy System which will have a hydrophilic coating on the external distal portion of the catheter shaft. The size range, intended purpose, and Indications for Use will be the same as the existing Auryon Atherectomy Catheters.

Device Description

The Auryon™ Atherectomy Catheters are single use catheters made of an array of optic fibers and surrounded by a circumferential blunt blade at its distal tip. The Auryon catheter is connected to the laser of the predicate device Auryon Atherectomy 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 Catheter must work over a commercially available 300cm 0.014" guide wire that crosses the lesion intra-

luminally. The new catheters which are the subject of this 510(k) include a hydrophilic coating on the external distal portion of the catheter shaft.

The predicate device Auryon Atherectomy Catheters are available in four sizes (0.9mm, 1.5mm, 2.0mm and 2.35mm, without hydrophilic coating. The subject device Auryon Atherectomy Catheters are available in the same four sizes (0.9mm, 1.5mm, 2.0mm and 2.35mm, but with a 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.

Indications 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 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 system.

Device Comparison	Subject Device: Auryon™ Atherectomy System (with Hydrophilic coating)	Predicate Device: Auryon Atherectomy System (K202835)	Reference Device: Auryon™ Atherectomy System (K221077)	Reference Device: Spectranetics Turbo-Elite Laser Atherectomy Catheters (K170059)
Indication for Use	The Auryon™ Atherectomy System and Auryon Atherectomy Catheters with	The Auryon Atherectomy System is intended for use in the	The Auryon™ Atherectomy System and Auryon Atherectomy Catheters with	The Turbo-Elite devices are indicated for use in the treatment, including

	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.	treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).	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.	atherectomy, of infrainguinal stenoses and occlusions. The 0.014" and 0.018" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).
Regulation Number	21 CFR §870.4875	21 CFR §870.4875	21 CFR §870.4875	21 CFR §870.4875
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	MCW	MCW	MCW	MCW
Catheter sizes	0.9mm, 1.5mm, 2.0mm, 2.35mm	0.9mm, 1.5mm, 2.0mm, 2.35mm	0.9mm, 1.5mm, 2.0mm, 2.35mm	0.9mm, 1.4mm, 1.7mm, 2.0mm, 2.3mm, and 2.5mm
Hydrophilic coating	Yes, all sizes	No	No	Yes, all sizes
Catheter Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Comparison of Performance Data

The hydrophilic coated Auryon Atherectomy Catheters were tested using the same methods and acceptance criteria as was done in the predicate device 510(k). In addition, coating performance was tested, with comparison to the performance of the reference device K170059. The specific tests are listed below

Summary of Performance Testing
Catheter shaft ID, OD, working length, and length of hydrophilic coating
Catheter trackability in simulated anatomical shape
Freedom from leakage during liquid infusion, and air leakage during aspiration (2.0 and 2.35mm sizes)
Pull testing of catheter tip and catheter to handle joints
Freedom from exposed optical fibers
Catheter torque test
Optical Functionality test
Coating Characterization
Coating integrity and particulate generation after simulated use

Substantial Equivalence

Assessment of the similarities and differences of the proposed hydrophilic coated Auryon Atherectomy Catheters and the predicate Auryon Atherectomy System and the reference device Spectranetics Turbo-Elite Laser Atherectomy Catheters 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 devices have the same Intended Use;
- The proposed and reference device K221077 have the same 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,
- The proposed and predicate catheters employ an identical overall design, essentially identical materials of manufacture, performance testing, sizes, and configurations.
- The proposed device and the reference device K170059 employ hydrophilic coatings that are similar in formulation, performance, and intended purpose (reduction of friction).

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.