December 2, 2020

Eximo Medical Ltd.
℅ James Welsh
Director, RA
AngioDynamics
603 Queensbury Avenue
Queensbury, New York 12804

Re: K202835
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: October 29, 2020
Received: November 2, 2020

Dear Mr. 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)*
K202835

Device Name
Auryon Atherectomy System

Indications for Use *(Describe)*
The Auryon Atherectomy System is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).

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: December 1, 2020

Sponsor

Eximo Medical Ltd
Pekeris St 3
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Contact

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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	**K181642**
Trade Name:	B-Laser 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 slight modification of the B-Laser Atherectomy System previously cleared under predicate 510(k) K181642; specifically, to modify the design of the existing 1.5 mm catheter to replace the current 100 µm diameter optical fibers with the same 70 µm diameter optical fibers that are in use for the other three catheter sizes (0.9 mm, 2.0mm, and 2.35mm) cleared via the predicate 510(k) K181642. In addition to the change in the diameter of the optical fibers, the length of the stainless steel tubing at the tip of the 1.5 mm catheter (the inner and outer blades) are slightly longer than for the predicate devce, without altering the overall length of the catheter.

Device Description

The Auryon™ Atherectomy System consists of two sub-units: 1) a single use catheter ("Auryon catheter"); and 2) a laser system. The Auryon catheter is a single use catheter that is 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 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 300cm 0.014" guide wire that crosses the lesion intra-luminally. 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. These devices should not be used in ISR cases.

The larger B-Laser™ 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 "offcenter" feature 2.35mm only). The aspiration feature is intended for debris and thrombus collection and removal from the vessel during the atherectomy procedure.

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/Intended Use

The Auryon™ Atherectomy System is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).

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 B-Laser Atherectomy system.

Device Comparison	Subject Device: Auryon Atherectomy System	Predicate Device: B-Laser Atherectomy System (K181642)
Indication for Use / Intended Use	The Auryon Atherectomy System is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).	The B-Laser Atherectomy System is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).
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
RFID for catheter identification	Included	Not Present
Dynamic stabilization of laser output power	Included	Not Present
Catheter sizes	0.9mm, 1.5 mm, 2.0mm, 2.35mm	0.9mm, 1.5 mm, 2.0mm, 2.35mm
Optical Fiber diameter	70 µm all sizes	100 µm for 1.5 mm catheter 70 µm all other sizes
Catheter Sterilization Method	Ethylene Oxide	Ethylene Oxide

Comparison of Performance Data

The modified 1.5 mm Auryon Atherectomy Catheter was 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 guard tube length
Catheter trackability in simulated anatomical shape
Freedom from leakage during liquid infusion
Pull testing of all joints
Freedom from exposed optical fibers
Catheter torque test
Optical Functionality test
Fatigue testing (the ability to deliver maximum energy for maximum duration without significant reduction in transmitted laser energy)
Electrical safety and EMC testing
Laser output power stabilization performance

Substantial Equivalence

Assessment of the similarities and differences of the proposed Auryon Atherectomy System and the predicate B-Laser Atherectomy Systems 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 and/or Intended Uses;
- 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 employ nearly 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 and have confirmed that there are no new questions of safety or effectiveness.