June 9, 2022

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

Re: K221077
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: April 11, 2022
Received: April 12, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221077

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: June 4, 2022

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

Subject Device

510(k) Reference	K221077
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

Reference Device

510(k) Reference	**K100462**
Trade Name:	Jetstream G3™ System, Jetstream G3™ L 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 revise the Indications for Use of the existing Auryon™ Atherectomy System. There are no physical changes to the device or software changes associated with the proposed change to the Indications for Use.

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 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 Auryon™ Atherectomy catheters are available in four sizes (0.9mm, 1.5mm, 2.0mm and 2.35mm):

- 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.

- 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.

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).

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	Predicate Device: Auryon™ Atherectomy System (K202835)	Reference Device: Jetstream G3 and G3L System (K100462)
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 is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).	The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from the upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac, or renal vasculature.
Regulation Number	21 CFR §870.4875	21 CFR §870.4875	21 CFR §870.4875
Regulatory Class	Class II	Class II	Class II
Product Code	MCW	MCW	MCW
Catheter sizes	0.9mm, 1.5mm, 2.0mm, 2.35mm	0.9mm, 1.5mm, 2.0mm, 2.35mm	1.6 mm, 1.85 mm, 2.1/3.0 mm, 2.4/3.4 mm

In addition to the change in indications described above, this 510(k) also included the following list of Letter to File changes that have been implemented since the clearance of the predicate device.

- As part of the tip polishing, a radius was added to the stainless steel outer blade.
- For the 2.0 and 2.35 mm catheters sizes, minor dimensional changes were made to the stainless steel guidewire tube and the inner blade to improve the process for welding these two parts together.

- The process for forming groves in the surface of the inner blades of the 2.0 and 2.35 mm catheters was changed from machining to laser etching.
- The dimensions of the guidewire connecting tube of the 2.0 and 2.35 mm catheters was adjusted to eliminate the potential for an internal step within the guidewire lumen.
- The allowed frequency tolerance for the RFID tag was reduced to reflect an improvement in the tag supplier's process.
- The mechanism which imparts the off-centering behavior to the tip of the 2.35 mm catheter was changed from stainless steel to nitinol.
- Within the laser console, a number of changes were made to improve manufacturability, reduce assembly costs, and improve mechanical robustness. None of these changes were to alter system behavior.
- Within the device software, improvements were made within the portions only accessible to service personnel.
- Software improvements were made to decrease the potential for nuisance errors.
- Within the device software the operation of the mechanical shutter is linked to the activation of the foot pedal.

Comparison of Performance Data

The modification to the Indications for Use statement associated with this 510(k) submission does not require any changes to the physical devices or device software. The testing conducted was performed on the subject devices for the purpose of generating data in support of the inclusion of a specific reference to thrombus removal within the Indication for Use statement.

Summary of Performance Testing
Fresh thrombus was created in simulated blood vessels, and then removed using the Auryon™ Atherectomy System and Auryon™ Atherectomy Catheters with Aspiration. Removal efficacy was based upon weight of thrombus removed. Confirmation that emboli are not generated during thrombus removal was based upon the absence of emboli in an in-line embolic protection device.

Substantial Equivalence

This 510(k) submission is limited to a change in the Indications for Use statement. There are no physical or software changes associated with the change in the Indications for use. The vessel occlusions that may be encountered during an Atherectomy procedure often include fresh thrombus as well as varying levels of calcification. The change in the wording of the Indications for Use associated with this 510(k) represents a clarification that the Auryon™ Catheters with Aspiration will remove a range of thrombus including fresh thrombus as well as more organized vessel occlusions.

The sum of the information provided in this submission has led 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.