April 10, 2026

Eximo Medical
Kasey Newcomb
Sr. Manager Regulatory Affairs
Pekeris St. 3
Rehovot, 7670203
Israel

Re: K260244
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: January 21, 2026
Received: January 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

KRINA M. PATEL -S
Digitally signed by KRINA M. PATEL -S
Date: 2026.04.10 12:29:14 -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.

510(k) Number *(if known)*
K260244

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 AURYON ATHERECTOMY SYSTEM

SPONSOR

Eximo Medical Ltd
Pekeris St 3
Rehovot, Israel 7670203

CONTACT

Kasey Newcomb
Sr.Manager, Global Regulatory Affairs
Eximo Medical Ltd / AngioDynamics, Inc

DEVICE NAME

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

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, resulting in the photoablation of infra-inguinal stenoses and occlusions in native and stented infra-inguinal arteries.

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

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. Additionally, the 0.9mm and 1.5mm catheters come in an extra-long length and a rapid exchange configuration where a guidewire port is positioned 45cm from the distal end. 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 and pulse parameters. There are no significant differences in the technological characteristics of the proposed device and predicate device which raised different questions of safety and effectiveness. ***Table 1*** below provides a comparison of the subject and predicate device.

Table 1. *Subject and Predicate Device Comparison*

Device Comparison	**Subject Device Auryon Atherectomy System**	**Predicate Device Auryon Atherectomy System**
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.
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/mm^2
Pulse Rate	40 Hz	40 Hz
Pulse Duration	10-25 ns	10-25 ns
Maximum output	33.5 mJ	33.5 mJ
Catheter Configurations	0.9mm, 0.9mm Extra Long (XL), 0.9mm Rapid Exchange (RX), 1.5 mm, 1.5mm Extra Long (XL), 1.5mm Rapid Exchange (RX), 1.7mm, 2.0mm, 2.35mm	0.9mm, 0.9mm Extra Long (XL), 1.5 mm, 1.5mm Extra Long (XL), 1.7 mm 2.0mm, 2.35mm
Radiographic marker	90% Pt / 10% Ir alloy tube, size 0.9mm, 0.9mm XL, and 0.9mm RX catheters only	90% Pt / 10% Ir alloy tube, size 0.9mm and 0.9mm XL only
Catheter Sterilization Method	Ethylene Oxide	Ethylene Oxide

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

Modifications made to the Auryon Atherectomy System were limited to introducing of the 0.9mm and 1.5mm Rapid Exchange Auryon Atherectomy Catheters with hydrophilic coating. There is no change to the principles of operations, 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 catheters did not impact or modify an existing risk no necessitate a new or modified risk.

COMPARISON OF PERFORMANCE DATA

The 0.9mm and 1.5mm Rapid Exchange Auryon Atherectomy Catheters were tested using the same methods and acceptance criteria as was done within the predicate device. Specific tests are listed below:

- Shaft Outer and Crossing Profile
- Catheter Shaft OD, ID, Working Length
- Guard Tube Length
- Catheter Trackability, Pushability, Kinkability (Functional Test)
- Shaft Pull Test
- Leakage
- Catheter Torque Strength
- Proximal Section Pull Test
- Optical Functionality Test
- Fatigue Test
- Catheter Optical Durability
- Evaluation of Hydrophilic Coating

STERILIZATION/SHELF LIFE/PACKAGING

The Auryon Atherectomy System catheters are sterilized via ethylene oxide (EO). A series of tests, performed by Eximo Medical and independent test houses, have been conducted to assess the suitability of the sterile packaging to protect the Auryon Atherectomy Systems and ensure sterility within its stated shelf life at point of use. These tests confirm the packaging integrity, sterility, and distribution cycle. Testing demonstrated that the packaging is robust enough to withstand extreme distribution conditions at extreme environmental conditions while maintaining packaging integrity and sterility. This submission does not impact the product's sterilization, shelf-life or packaging.

BIOCOMPATIBILITY

The Auryon Atherectomy System Catheters are a sterile single-use disposable instrument. The Auryon Atherectomy System Catheters have met the biocompatibility testing requirements identified in ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process. Specifically, the following tests were performed with acceptable results; cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, and hemocompatibility. This submission does not impact the product's biocompatibility.

CONCLUSION

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

- The proposed and predicate device have the same Pro-Code, Regulation Number, Regulation Name, and Regulatory Class;
- 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.