October 5, 2018

Eximo Medical Ltd.
% Dr. Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K181642
Trade/Device Name: B-Laser Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: July 10, 2018
Received: July 10, 2018

Dear Dr. Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eleni Whatlev 2018.10.05 11:04:59 -04'00'

For

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181642

Device Name
B-Laser Atherectomy System

Indications for Use *(Describe)*
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).

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

Eximo Medical Ltd.'s B-Laser™ Atherectomy System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 21, 2018

Name of Device

B-Laser™ Atherectomy System

Common or Usual Name

Peripheral Atherectomy Catheter

Classification

21 CFR 870.4875, Class II, product code MCW

Predicate Devices

Spectranetics Turbo-Tandem System and Turbo Elite Laser Catheters (K140775) (Primary Predicate)

Phoenix® Atherectomy System (K132682) (Reference Device)

Intended Use / Indications for Use

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).

Device Description

The B-Laser™ System consists of two sub-units: 1) a single use catheter ("B-Laser™ catheter"); and 2) a laser system. The B-Laser™ 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 B-Laser™ 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 B-Laser™ System must work over a commercially available 300cm 0.014" guide wire (GW) that crosses

the lesion intraluminally. - 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. Please note that 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 "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.

Comparison of Technological Characteristics

The B-Laser™ System has similar technological characteristics as its predicate devices. Both the B-Laser™ System and the primary predicate device have similar components. Both the subject and primary predicate device include two sub-units consisting of a catheter component and an external laser system. The external laser systems for both devices connect to the catheter and transmit laser pulses through the catheter to ablate the target lesion. Both the B-Laser™ System and the primary predicate transmit laser at similar fluence levels to the lesion (50 and 60mJ/mm^2 for the B-Laser™ System versus 30-80 mJ/mm^2 for the primary predicate). It should be noted that the fluence levels for the B-Laser™ System are within the fluence levels cleared for the primary predicate device. Although the specific wavelengths and pulse repetition rates differ, these minor differences do not adversely impact performance, as confirmed in performance testing.

Both the B-Laser™ System and its primary predicate are intended for similar vessels of the infrainguinal area at a diameter range that starts at 1.4 mm. Further, both the subject and the primary predicate have similar catheter diameters that are compatible with sheath sizes of 4F-7F for the subject device and 4F-8F for the primary predicate. The B-Laser™ System and primary predicate have similar working lengths (125 to 150 cm for the B-Laser™ System versus 112-150 cm for the primary predicate). In addition, the subject device and the primary and reference devices are over-the-wire catheters that are compatible with 0.014" guidewires, are sterilized using ethylene oxide, and are for single use only.

The B-Laser™ System and the reference device, Phoenix® Atherectomy System (K132682), have similar technological characteristics. They are both designed for atherectomy of the peripheral vasculature. Further, both the 2.0 mm and 2.35 mm catheters sizes of the B-Laser™ System and the reference device have debris collection and removal mechanisms. Although the subject device uses vacuum aspiration whereas the reference device continuously collects and removes the excised debris by mechanical conveyance using an Archimedes Screw, this difference does not raise new questions of substantial equivalence. Lastly, both the subject device and the reference device are indifferent to the presence of contrast media.

Therefore, the subject B-Laser™ System has very similar technological characteristics as its predicates.

Performance Testing Summary

The following nonclinical and clinical performance testing has been conducted to support the substantial equivalence of the B-Laser™ System to its predicate devices. In all instances, the B-Laser™ System functioned as intended.

- Sterilization Validation was established in accordance with ISO 11135, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 11737-2, and EN 556-1.

- Package integrity and accelerated aging studies were completed in accordance with ISO 11607-1, ASTM D 4169-16 and ASTM D 5276-98 (2009), F88-15, EN 868, ASTM D 4332-14, ASTM 1929-15, and ASTM D 999-08.

- Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993-1 and included cytotoxicity, irritation, sensitization, acute systemic toxicity, hemocompatibility (direct contact and extract method, in vivo thrombogenicity and PTT), complement activation, pyrogenicity and LAL tests.

- Software verification and validation was performed, and demonstrated that the software performs as intended.

- Electrical safety and electromagnetic compatibility testing were conducted and results were passing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-2-22, and IEC 60601-1-6.

- Functional bench testing was conducted after sterilization, transportation simulation and 1-year accelerated shelf-life (including demonstrated compliance with relevant standards such as ISO 10555-1). The following tests were performed (those noted with asterisks were performed only at base line): Shaft outer diameter and crossing profile; shaft inner diameter; shaft working length; guard tube length; catheter trackability, pushability, kinkability and guidewire pushability; leakage test; shaft pull test; inner blade pull test; proximal section pull test; luer pull vs handle pull test; corrosion test*; distal tip evaluation; optical functionality test; radio-detectability*; torque strength; optical validation; optical durability test; ISR testing*; optical fiber fatigue test; and penetration and aspiration tests of the 2.0mm and the 2.35mm catheters*.

- In vivo GLP testing in animal models was performed to evaluate and establish the safety of the B-Laser™ System. The testing (acute and sub-chronic) was performed in naïve external and internal iliacs arteries of domestic pigs. Safety measures were: vessel injuries (gross pathology and histopathology) following activation of the B-Laser™ at highest energy, thrombogenicity, presence of distal embolization at all anatomical levels, general health and general gross pathology.

Clinical Testing

Clinical evaluation of the device in the intended population was performed in a prospective, single-arm, multi-center, open-label, non-randomized clinical study in 50 subjects in Europe, as well as in a pivotal, prospective, single-arm, multi-center, open-label, non-randomized IDE clinical study in 97-subjects in US and Europe.

In the pilot study, the results presented 100% success in crossing the target lesions (52/52 lesions in 49 subjects) and residual stenosis reduction of 35.04% on average as determined by retrospective evaluation by independent Corelab. There were no device related perioperative clinically significant adverse events (0%), and there were no major adverse events (MAE) (0%) to 30-days and 6-months post procedure, and only 2 cases (4.3%) of MAE (one target lesion revascularization, at 384 days post procedure and a second TLR was a planned revascularization with surgical by-pass due to recurrent symptoms of chronic ischemia after the completion of 1 year follow-up) amongst 46 subjects that completed the 1 year post procedure follow-up. Further, there were no device related adverse events. Eighteen serious adverse events (SAEs) were reported during the course of the study in 14 subjects that were unrelated to the subject B-Laser™ catheter.

In the pivotal study, the safety and effectiveness primary endpoints were achieved. There was only 1 MAE at 30 days (death, not related to the device) out of 97 subjects (1.03%) and the average reduction of residual stenosis was 33.6% (14.2% SD) out of the 95 evaluable subjects(or 107 evaluable lesions). There were only 11 type A and 5 type B dissections, and 1 case of transient spasm and 1 case of transient staining after the use of the device, none of which require intervention, with regards to the secondary safety endpoint. No other device related perioperative complications were noted or reported.

Substantial Equivalence

The B-Laser™ System has the same intended use and very similar indications for use, technological characteristics, and principles of operation as its predicate devices. Performance testing, including functional testing, simulated use testing, in vivo GLP testing in animal models, and clinical testing demonstrated it to be at least as safe and as effective as the predicate and that the minor differences in technology do not raise new questions of safety or effectiveness. Thus, the B-Laser™ System is substantially equivalent to the predicate devices.