October 7, 2022

Endymed Medical, Ltd.
Ohad Fisher
Regulatory Affairs Director
12 Leshem St. North Industrial Park, PO Box 3582
Caesarea, 3088900
Israel

Re: K222369
Trade/Device Name: PURE Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 1, 2022
Received: September 1, 2022

Dear Ohad Fisher:

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,

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K222369

Device Name
PURE Laser

Indications for Use *(Describe)*
Indications for use for the Pure Laser diode hair removal system with a 810nm applicator include:
• Hair removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
• Treatment of Pseudo folliculitis Barbae (PFB)
• Use on all skin types (Fitzpatrick I-VI)

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
PURE Laser - K222369

This 510(K) Summary of safety and effectiveness for the PURE Laser is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant	EndyMed Medical Ltd.
Address	12 Leshem St. North Industrial Park. P.O. Box 3582 Caesarea 3088900 Israel
Contact Person	Ohad Fisher, Regulatory Director
Contact Information	ohadf@endymed.com 972-4-6309122
Preparation Date	August 5, 2022
Device Trade Name	PURE Laser
Classification Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810
Product Code	GEX
Regulatory Class	II
Legally Marketed Predicate Device	Elysion-pro (K193367)

Device Description:

The ***PURE Laser*** system is a non-invasive diode laser based system used for Hair Removal. The system is based on a single wavelength laser diode built-in a HP, with a 10x10mm spot size and ability to control the pulse width, frequency and power. The Hair Removal Laser is intended for use on all skin types (Fitzpatrick skin types I-VI).

The device is sold with an electroconductive gel with prior FDA clearance – EndyGel (K161715).

Indications for use:

Indications for use for PURE Laser diode laser hair removal system with 810nm applicator includes:

- Hair Removal with Static (Regular) and Dynamic (DioGlide) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
- Treatment of Pseudo folliculitis barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI).

Substantial Equivalence—Technological Characteristics:

Specification	Pure Laser (Subject Device)		Elysion-pro (K193367)		Comparison
Wavelength	810nm		810nm, 755nm		810nm wavelength is the same. The PURE laser does not include a 755nm handpiece.
Modes	Regular Mode (Static)	DioGlide (dynamic)	Static	dynamic	Same
Fluence	5-50J/cm^2	6-10J/cm^2	40J/cm^2 (can go to 70J/cm2)		Similar. The predicate device fluence can be as high as 70J/cm2, but it states that treatment is conducted up to 40J/cm2.
Repetition Rate	1-14Hz		3Hz - 15Hz		Similar. The predicate device has a slightly higher range for its dynamic function, but the high-end repetition rate for the Pure Laser (14Hz) is within the range of the predicate.
Spot Size (mm x mm)	10x10		10x10, 18x10		Similar. The Pure laser has only one spot size, which is identical to the static spot size of the predicate. The difference in spot size for the dynamic function is minimal and does not impact the safety or efficacy of the device.
Pulse duration	18-180ms		3-400ms		Similar. The pulse duration of the Pure Laser is within the range of the predicate device.
Cooling Mechanism	Thermoelectric cooling		Thermoelectric Cooling		Same.

Performance Testing
Verification and validation activities were successfully completed and establish that the PURE Laser performs as intended. Testing included the following:

IEC 60601-1:2005 (Third Edition) + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests

60601-2-22 Edition 3.1 2012-10 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 62304:2006 Ed.1.0 – Medical device software – software life cycle processes

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Conclusion

While the devices have minor differences in the technical specifications, the PURE Laser specifications are within the range of the predicate device's specifications. The two laser perform with the same principle – higher fluence and low repetition rate for treatment of small areas on the body, and lower fluence with high repetition rate for treating large areas on the body with the dynamic mode. The differences allow for the clinician performing treatment to select the best treatment parameters for the skin/hair type and do not impact the safety and efficacy of the device. Based on the comparison and analysis above, the PURE Laser is determined to be substantially equivalent to the predicate device.