December 13, 2022

Epilady 2000 LLC
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

Re: K213105
Trade/Device Name: Epilaser Absolute
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: November 10, 2022
Received: November 10, 2022

Dear John Smith:

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 -S

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)*
K213105

Device Name
Epilaser Absolute

Indications for Use *(Describe)*
Epilaser Absolute is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Epilaser is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

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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K213105

510(k) SUMMARY

Epilady 2000's Epilaser Absolute

Submitter

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Date Prepared: November 10, 2022

Device Trade Name: Epilaser Absolute

Common or Usual Name: Powered laser surgical instrument

Classification Name: 21 CFR 878.4810, Class II, GEX , Laser surgical instrument for use in general and plastic surgery and in dermatology

Predicate Devices

K170790 Epilaser

K141063 LinScan System

Device Description

The Epilaser Absolute is an over-the-counter, hand-held, hair removal device. It kills the root of the hair follicle using laser energy at 808 or 980nm. The system is designed to be manually targeted onto individual hairs and the laser activates when it is pressed against the skin. A skin tone sensor ensures the user has the correct skin tone prior to laser activation.

Indications for Use

Epilaser Absolute is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Epilaser is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

Summary of Technological Characteristics

Both the Epilaser Absolute and its predicates use light energy for permanent hair reduction. The primary difference between the originally cleared Epilaser and the subject Epilaser Absolute are the addition of a 980 nm model and a modification to the user interface. Use of 980 nm light to permanently remove hair in darker skin types has been cleared in many other laser systems, including the Linscan System (K141063). The Absolute has a spot size, peak power, fluence, and pulse duration within the range or lower than what has been cleared for the predicates. The company has performed laser safety testing per IEC 60601-2-22 and IEC 60825-1 to show continued safety of the modified laser systems.

The user interface differs between original Epilaser and the Absolute. Although the user interface has been modified as compared to the predicate Epilaser (K170790), the interface has been significantly simplified. This is consistent with the activation mechanism used by the TRIA (K120737). The company has performed usability testing to demonstrate continued OTC use.

Performance Data

The following tests were conducted to establish substantial equivalence:

- Biocompatibility testing per ISO 10993-5 (cytotoxicity) and ISO 10993-10 (sensitization and irritation).
- Software documentation and validation per “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.
- Electrical, EMC, and laser safety testing per AAMI/EN 60601-1, AAMI/EN IEC 60601-1-2, IEC 62471, IEC 60825-1, and IEC 60335-2-23.
- Skin tone sensor validation
- Self-selection and usability human factors testing

Conclusions

The Epilaser Absolute has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in technical characteristics do not raise different questions of safety and effectiveness when used as labeled. Performance data demonstrate that the Epilaser Absolute is substantially equivalent to predicate devices.