DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 1, 2017

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

Re: K170970
Trade/Device Name: Epilaser
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: June 23, 2017
Received: June 23, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K170970

Device Name
Epilaser

Indications for Use *(Describe)*
Epilaser 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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K170970
510(k) SUMMARY

Epilady 2000's Epilaser

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

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Date Prepared: August 29, 2017

Name of Device

Epilaser

Common or Usual Name

Powered laser surgical instrument, GEX

Classification Name

21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology, class II

Predicate Devices

TRIA Laser Hair Removal System, TRIA Beauty, Inc. (K090820, K120737)

Device Description

The Epilaser is an over-the-counter, hand-held, hair removal device intended for hair removal on the face below the nose, underarms, and bikini line. It kills the root of the hair follicle using focused laser energy. The system has an integrated microscope and external viewing screen which allows the user to visualize and target individual hairs. The system is composed of a hand held laser containing multiple safety features and a dedicated viewing screen.

Intended Use/Indications for Use

Epilaser 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

The Epilaser is composed of four lasers, a focusing objective, a microscope subassembly, a mechanical key lock, an operation button, an electro-optical sensor, a touch sensor, a battery, an LED, and housing.

The Epilaser is substantially equivalent to the TRIA Laser Hair Removal System, TRIA Beauty Inc. (K090820, K120737). The Epilaser has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Importantly, the two systems have identical laser output parameters. The systems primarily differ in that the Epilaser uses a microscope objective to allow the user to target individual hairs, whereas the predicate system treats a larger area. The minor technological differences between the Epilaser and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Epilaser is substantially equivalent to the TRIA.

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, IEC 60335-2-23, and EN 55014-1.
- Usability testing that showed that all subjects were successful at determining who should use the device and on what anatomic locations the device should be used. In addition, the intended users were successful at performing all critical tasks, with only one user failing in one of the tasks due to abandoning the instructions in the middle of the procedure. This subject was able to perform the task after completely reading the instructions.
- Laser energy deposition at various depths characterization

Conclusions

The Epilaser has the same intended use and identical laser output parameters to the predicate TRIA laser. Safety testing has shown that the Epilaser conforms to applicable electrical, EMC, and laser safety standards. Usability testing demonstrated that users can self-select and use the device. Therefore, the Epilaser is substantially equivalent to the predicate device.