January 27, 2024

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

Re: K233224
Trade/Device Name: Epilaser Pro
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: December 29, 2023
Received: December 29, 2023

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S 2024.01.27 21:26:01 -05'00'

Tanisha Hithe
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)*

K233224

Device Name

Epilaser Pro

Indications for Use *(Describe)*

Epilaser Pro 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K233224

510(k) SUMMARY

Epilady 2000's Epilaser Pro

Submitter

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Date Prepared: January 17, 2024

Device Trade Name: Epilaser Pro

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

K170970 Epilaser
K213105 Epilaser Absolute

Device Description

The Epilaser Pro 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 includes an algorithm that automatically targets individual hairs over the treatment area 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 Pro 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 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 Pro and its predicates use light energy for permanent hair reduction. Like the Epilaser Absolute (K213105), the subject Epilaser Pro comes into two varieties, Brunette and Dark, which differ in regard to the wavelength of light they emit and the skin tones they can treat (I-IV or V-VI, respectively). The primary difference between the previously cleared Epilaser systems and the subject Epilaser Pro is the addition of an automatic hair targeting algorithm and a modification to the user interface. The company has performed validation testing to demonstrate equivalent targeting performance as compared to manual use and equivalent usability.

The Epilaser Pro has a spot size, peak power, fluence, and pulse duration that matches 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 differ between the predicates and the Pro.

Performance Data

The following tests were conducted to establish substantial equivalence:

- Biocompatibility testing per ISO 10993-1 to assess cytotoxicity, 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.
- Targeting algorithm validation to demonstrate that the algorithm detects target hairs and avoids pigmented/tattooed regions at least equivalently to the predicate (see clinical efficacy test below)
- Self-selection and usability human factors testing

Clinical Testing

Two clinical evaluations were performed, one to assess safety and one to assess performance.

- A worst-case safety test to evaluate the risk of multiple treatments of the same hair was completed. Testing was performed on 44 evaluable subjects with skin types varying from type I – VI. Each subject had three treatment areas, where each hair was treated once, twice, or three times. Treatments were performed at the maximum fluence. Immediate, 24 and 72-hour, one week, and one month post treatment results were assessed by taking a digital photograph and assessing the treatment area for adverse effects. Pain during treatment was also assessed using VAS. All observed responses consisted of, at most, mild erythema and/or mild blistering that spontaneously resolved within 48 hours.

- An efficacy study was performed on 69 subjects of all skin types (Fitzpatrick scale I-VI). To objectively determine the location and number of hairs, pigmented spots and tattoos, and skin tone, the treatment area was pictured via a dermatoscope by a dermatologist. The dermatologist identified location of hairs and pigments as well as the skin tone to define the “Ground Truth”. The study compared the performance of the subject and predicate devices to the objective “Ground Truth” as well as to each other. Subjects received simulated treatments to 6 different areas on the body – legs, arms, face below the nose, underarms, bikini line and chest, consistent with the device’s indications. 87 treatment areas were studied in which 25 treatment areas included pigmented spots and 26 treatment areas include tattoos. The subject device has above 90% True Hits and greater number of True Hits than the predicate, and a smaller number of False Hits than the predicate an no Not Safe Hits. The skin tone was also correctly identified in all subjects, validating the skin tone sensor.

Conclusions

The Epilaser Pro 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.