Pulsaderm LLC
Gloria Avendano
Regulatory Affairs Manager
12801 Commonwealth Dr. Units 2-6
Fort Myers, Florida 33913

Re: K182501
Trade/Device Name: Hair Laser Headband
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 12, 2018
Received: September 12, 2018

October 26, 2018

Dear Gloria Avendano:

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,

Neil R Ogden -S
2018.10.26 10:23:41 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Hair Laser Headband

Indications for Use *(Describe)*
The Laser Headband is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of 11a to V patterns of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale 1-4, 11-1, 11-2, or frontal, both with Fitzpatrick Skin Types I to IV.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FDA 510(k) Summary of Safety and Effectiveness for The Hair Laser Headband

General Information

Submitter:
Pulsaderm LLC
12801 Commonwealth Dr. Units 2-7
Fort Myers, Florida 33913

Contact Person:
Gloria Avendano
Regulatory Affairs Manager
Pulsaderm LLC
12801 Commonwealth Dr. Units 2-7
Fort Myers, Florida 33913
Gloria@pulsaderm.com

Summary Preparation Date:

Device

Device Name:	Hair Laser Headband
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and in Dermatology
Regulation Numbers:	21 CFR 890.5550
Regulatory Class:	II
Product Codes:	OAP

3. Predicate Devices:

The Laser Headband is substantially equivalent to the following predicate devices;

Device	510(k) Number	Manufacturer
NutraStim Hair Laser Helmet	K160728	Pulsaderm LLC

Device Description
Similar to the Hair Laser Helmet, the Hair Laser Headband is a low-level laser device and is intended/indicated for over- the –counter use. The device emits laser light with the intention to promote hair growth. The device provides distributed laser light to the scalp at 655 +/- 5 nanometers with an individual laser output of 5mW per laser diode. The lasers are configured inside a headband, designed for hands-free operation during treatment. The laser headband is for portable use with rechargeable battery.

Intended Use and Indications:
The Hair Laser Headband is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.

Technological Characteristics
The Hair Laser Headband shares the exact same fundamental scientific technology characteristics to the Hair Laser Helmet. The only modifications are the following:

- Size and dimensions change
- Reduce number of diodes

The main technological characteristics in the Hair Laser Headband remain the same, such as wavelength and output of laser diodes, treatment time, treatment regimen, materials, delivery method, indications for use, helmet-like design, single on/off push button, and both devices use a rechargeable battery.

The modifications mentioned above have no effect in the safety or efficacy of the Hair Laser Headband as users are instructed to move the device in three different sections of the head to achieve the same surface treatment as the Hair Laser Helmet.

Performance Data:
Similar to the Hair Laser Helmet, the Hair Laser Headband complies with the following test standards:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements.

Based on the nature of modifications implemented, the Hair Laser Headband underwent bench testing and results indicate that the Hair Laser Headband shares the same output parameters and dose rate characteristics as the Hair Laser Helmet.

Design verification and design validation testing were performed according to FDA's Design control activities per 21 CFR 820.30. Additionally, Risk Management activities were performed according to ISO 14971:2012 to evaluate new risks from design changes and all residual risks were found to be acceptable.

In all instances, the Hair Laser Headband performed as intended.

Substantial Equivalence

The Hair Laser Headband shares the same technological characteristics as the Hair Laser Helmet K160728:

Device	Hair Laser Headband	Hair Laser Helmet
510 (k) Number	pending	K160728
Product Code	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500
Legal Manufacturer	Pulsaderm LLC	Pulsaderm LLC
Device Type	Portable headband sits on patient's head	Portable helmet sits on patient's head,
Indications for Use	Indicated to treat Androgenetic Alopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.	Indicated to treat Androgenetic Alopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.
Type of Use	Over the Counter	Over the Counter
Number of Laser Diodes	40	82
Wavelength	655 +/- 5 nanometers	655 +/- 5 nanometers
Laser Classification	Class 3R	Class 3R
Treatment Protocol	20 Minutes- 3 times a week	20 Minutes- 3 times a week
Standards Applied	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 ISO 14971	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 ISO 14971
Device Class	Class II	Class II
Sterilization	Basic cleaning, instructions provided.	Basic cleaning, instructions provided.
Common Name	Lamp, Non-Heating	Lamp, Non-Heating

The minor modifications in dimensions and number of diodes have no effect in the safety or efficacy of device, as confirmed with performance testing and risk analysis activities.

Conclusion:
Based upon the indications for use and data provided in this pre-market notification, all functional modes of the Hair Laser Headband have been shown to be substantially equivalent to the Hair Laser Helmet with respect to intended use, technological characteristics and safety characteristics. Pulsaderm LLC believes that no significant differences exist between the device and the predicate. Therefore, Substantial equivalency is requested.