DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 8, 2017

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

Re: K170111
Trade/Device Name: Pulsaderm Acne Mask 28, Pulsaderm Acne Mask 37
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: OLP
Dated: April 10, 2017
Received: April 11, 2017

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. 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 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 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,

Jennifer R. Stevenson -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)*
K170111

Device Name
Pulsaderm Acne Mask 28 and Pulsaderm Acne Mask 37

Indications for Use *(Describe)*
The Pulsaderm Acne Mask 28 and Pulsaderm Acne Mask 37 are intended for over the counter use for the treatment of mild to moderate acne.

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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510(k) Summary

Pulsaderm Acne Mask 28, Pulsaderm Acne Mask 37

1. General Information

Submitter:
Pulsaderm LLC
12801 Commonwealth Dr. Units 2-6
Fort Myers, FL 33913

Contact Person:
Gloria Avendano
Regulatory Affairs Manager
Pulsaderm LLC
239-208-7549
Gloria@pulsaderm.com

Summary Preparation Date: December 1st, 2016

2. Device

Device Name:	Pulsaderm Acne Mask 28 and Pulsaderm Acne Mask 37
Common/Usual Name:	Acne Light Therapy System
Classification Name:	Over the Counter powered Light Based Laser for Acne
Classification Regulation:	21 CFR 878.4810
Classification Panel:	General and Plastic Surgery
Code:	OLP
Device Class:	II

3. Predicate Devices:

Device Name	K Number	Manufacturer
Illumask Acne Light Therapy System	K123999	La Lumiere, LLC

4. Device Description:

Pulsaderm Acne Mask 28 and Pulsaderm Acne Mask 37 are class II Medical Devices that use Light Emitting Diodes to apply low power monochromatic and non-coherent light in the red and blue range, to treat mild to moderate acne. The devices are powered by Ni-MH rechargeable batteries.

5. Indications for Use:

The Pulsaderm Acne Mask 28 and Pulsaderm Acne Mask 37 are intended for over the counter use for the treatment of mild to moderate acne.

6.Technological Characteristics and substantial equivalence:

Pulsaderm Acne Mask 28 and Acne Mask 37 share the same methods of operation, similar indications for use and similar treatment regimen as predicate K123999.

The reference table below shows that the devices share similar output and technology characteristics

Device Name	Pulsaderm Acne Mask 28	Pulsaderm Acne Mask 37	Illumask Acne Light Therapy
510 (k) Number	**Pending**	**Pending**	**K123999**
Indications for Use	Intended for over the counter use for the treatment of mild to moderate acne.	Intended for over the counter use for the treatment of mild to moderate acne.	Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne
Wavelength	Red: 630 +/- 5 nm Blue: 440 +/-5 nm	Red: 630 +/- 5 nm Blue: 440 +/-5 nm	Red: 630 nm +/- 5 nm Blue: 440 +/- 5 nm
OTC/Prescription	OTC	OTC	OTC
Waveform	Constant	Constant	Constant
Rechargeable	Yes, Ni-MH Batteries	Yes, Ni-MH Batteries	NO
Number of LED Diodes	28	37	21
Total energy delivered per treatment session	20.44 j/cm²	22.72 j/cm²	21.94 j/cm²
Treatment protocol	10 minutes everyday	10 minutes everyday	10 minutes everyday
Total Treatments required	30	30	30

7. Performance Data:

Performance testing was conducted and confirm compliance to design specifications; similar wavelength, energy type and safety characteristics.

Pulsaderm Acne Masks 28 and Pulsaderm Acne Mask 37 were tested and found in conformance with test standards: IEC 60601-1, IEC 60601-1-2, and IEC 62471. Biocompatibility testing to ISO 10993.

Pulsaderm Acne Mask 28 and Acne Mask 37 were designed and developed under a quality management system conforming to ISO 14971.

8. Non-clinical-testing

A lay-user study and self-selection study was conducted with Institutional Review Board (IRB) approval and oversight to determine if lay users could read the product labeling and then self-assess if the Pulsaderm Acne Mask 28 and 37 would be beneficial for them to use. Study data was collected and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended. The performance data supplied in this 510(k) demonstrated that the majority of lay users were able to properly self-select themselves using the box labeling and the majority of lay users were able to properly use the device by reading instructions in the user manual without any assistance.

In summary, the conclusion was that an average lay user can read and comprehend correctly the user manual and package labeling.

9. Conclusion

Based upon the analysis of the performance characteristics, safety characteristics and intended use for the Pulsaderm Acne Mask 28 and Acne Mask 37, Pulsaderm LLC believes that no significant differences exist between these devices and the predicate K123999. Therefore, Pulsaderm Acne Mask 28 and Acne Mask 37 are substantially equivalent to the predicate.