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

April 14, 2017

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

Re: K163329
Trade/Device Name: Pulsaderm Wrinkle Mask 28, Pulsaderm Wrinkle Mask 72
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: OHS
Dated: March 10, 2017
Received: March 13, 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,

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)*
Pending

Device Name
Pulsaderm Wrinkle Mask 28, Pulsaderm Wrinkle Mask 72

Indications for Use *(Describe)*
The Pulsaderm Wrinkle Mask 28 and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I,II and/or III.

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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510(k) Summary

Pulsaderm Wrinkle Mask 28, Pulsaderm Wrinkle Mask 72

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
Gloria@pulsaderm.com

Summary Preparation Date: March 10, 2017

2. Device

Device Name:	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72
Common/Usual Name:	Wrinkle Light Therapy System
Classification Name:	Light Based Over the Counter Wrinkle Reduction
Classification Regulation:	21 CFR 878.4810
Classification Panel:	General and Plastic Surgery
Code:	OHS

3. Predicate Devices:

Device Name	K Number	Manufacturer
Pro X OTC 5 Light Therapy	K140471	La Lumiere, LLC
Quasar Calypso C100 Wrinkle Reduction Device, Baby Quasar Plus, Quasar MD Plus	K130225	Silver Bay, LLC

4. Device Description:

The Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72 are over the counter devices and consist of a collection of red and infrared diodes for the treatment of facial wrinkles. Pulsadern Wrinkle Masks 28 and 72 are powered rechargeable Ni-MH batteries. To receive treatment, the user simply places the mask over the face for a specific period to receive treatment.

5. Indications for Use:

The Pulsaderm Wrinkle Masks 28 and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III.

6.Technological Characteristics and substantial equivalence:

Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72 share the same indications for use, treatment regimen as the predicate devices. Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72 are as safe and effective as the predicate devices. Pulsaderm LLC is certain that the difference in number of diodes and slightly increase in power output does not affect the safety or efficacy of the device as there are a wide range of number of diodes and power output in predicate K130225 and devices cleared under device code OHS.

Based on technology, similar design, wavelength parameters and treatment regimen the different number of LED Diodes between devices does not adversely affect the safety of the devices.

Device Name	**Pulsaderm Wrinkle Mask 28**	**Pulsaderm Wrinkle Mask 72**	**Pro X OTC 5 Light Therapy Device**	**C100, Baby Quasar Plus and Quasar MD Plus**
Indications for Use	The Pulsaderm Wrinkle Mask 28 is intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and/or III.	The Pulsaderm Wrinkle Mask 72 is intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and/or III.	Intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have Fitzpatrick Skin Types I, II and III.	Intended to emit energy in the RED/IR spectrum, specifically for the treatment of full-face wrinkles.
Wavelength	620-630 nm red and 850 nm Infrared	620-630 nm Red and 850 nm Infrared	620-630 nm Red and 850 nm Infrared	610 nm Red and 850 nm Infrared
Waveform	Constant	Constant	Constant	Constant
Number of LED's	28	72	18	70, 40 and 24
Rechargeable	Yes, Ni-MH Batteries	Yes, Ni-MH Batteries	NO	Yes, Ni-MH Batteries
Power Density (mW/cm^2)	Red: 15.94 Infrared: 5.24	Red: 18.71 Infrared:6.61	Red: 13.20 Infrared: 6.60	unknown
Total power (mW/cm^2) for entire mask	21.18	25.35	19.80	unknown
Total energy per 15-minute treatment session	0.10 joules	0.11 joules	0.09 joules	unknown
Overall total Energy for 60 treatments (J)	5.75 J	6.87 J	5.37 J	Unknown
Treatment protocol	15 minutes everyday	15 minutes everyday	15 minutes everyday	3 minute per treatment per area. Daily.
Number of treatments device will allow	60 or more	60 or more	30 sessions per device	60 or more

The reference table above will confirm the devices share similar output and technology characteristics.

7. Performance Data:

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

Pulsaderm Wrinkle Masks 28 and Wrinkle Mask 72 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 Wrinkle Masks 28 and Wrinkle Mask 72 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 Wrinkle Masks 28 and 72 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 Wrinkle Masks 28 and 72, Pulsaderm LLC believes that no significant differences exist between this device and the predicates. Therefore, substantial equivalency is requested.