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

July 12, 2017

Dermal Photonics Corporation
Mr. David Bean
CEO
5 Elm St, Suite 10
Danvers, Massachusetts 01923

Re: K163137
Trade/Device Name: Nira Beauty Skin Laser
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: June 8, 2017
Received: June 12, 2017

Dear Mr. Bean:

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 -S3

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)*
K163137

Device Name
NIRA Beauty Skin Laser

Indications for Use *(Describe)*
The NIRA Beauty Skin Laser is indicated for the treatment of periorbital wrinkles.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)

A) Submitted by: Dermal Photonics
5 Elm Street, Suite 10
Danvers, MA 01923

Official Contact: David Bean
CEO
dbean@dermalphotonics.com
(781) 451-1701

B) Classification Names: Light based Over the Counter Wrinkle Reduction

Proprietary Name: NIRA Beauty Skincare Laser

Device Class: Class II

Regulations: 21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

Product Codes: OHS

Classification panel: General & Plastic Surgery

C) Primary Predicate: K090525 Palomar LOI System

D) Date Prepared: April 27, 2017

E) Device Description:
The NIRA Beauty Skincare Laser is a hand-held reusable OTC non-fractional diode laser device employing 1450 nm wavelength. The NIRA Laser consists of a hand piece, wall-plug battery charger, and USB cable. The hand piece fits in the hand and the laser light comes out of the tip. There is a single micro-USB connector interface that provides two functions: battery charging and USB communication (for charging).

E) Intended Use/Indications For Use:
The NIRA Beauty Skincare Laser is indicated for the treatment of periorbital wrinkles.

F) Substantial Equivalence Comparison and Discussion

	Dermal Photonics NIRA Beauty Skincare Laser K163137	**Palomar LOI System K090525**
Product code	**OHS**	**ONG**

	Dermal Photonics NIRA Beauty Skincare Laser K163137	**Palomar LOI System K090525**
Indications for Use	The NIRA Laser is indicated for the treatment of **periorbital wrinkles.**	The LOI System is an over-the-counter device intended for treatment of **periorbital wrinkles**.
OTC	Yes	Yes

Similarities
The NIRA Laser has similar indications for use, is an OTC device and uses a similar wavelength as the predicate device.

The NIRA Laser has similar clinical efficacy three (3) months after users stopped using NIRA, similar to the Palomar LOI System.

Like the predicate device, the NIRA Laser meets all electrical, EMC, or Laser, and FCC testing requirements.

Differences
Differences between the NIRA Laser and the predicate devices include:

- Pulse/treatment duration
- Treatment schedules

Conclusion
Differences between the NIRA Laser and the predicate device do not raise different issues of safety or effectiveness. The NIRA Laser was demonstrated in a clinical study to be safe and effective and meet its indication for use. The NIRA Laser is substantially equivalent to the predicate devices.

G) Performance Testing
No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Bench
The NIRA Laser meets all electrical, EMC, or Laser, and FCC testing requirements. Software documentation was provided consistent with FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11. 2005 and a Moderate Level of Concern

Human – Self Selection and Usability
A Self-selection study successfully assessed whether or not naive laypersons could correctly determine (self-select) if they are appropriate candidates for use of the NIRA device based solely on reading the box labeling.

A Usability study successfully assessed that the NIRA Laser is usable by the device's intended users in a simulated use environment.

Human – Clinical
A clinical study was conducted. The clinical study for periorbital wrinkles was a 76 subject, open-label comparison to baseline effectiveness, and safety study.

Efficacy
Periorbital treatment met its predefined clinical and statistical endpoint with a median reduction of 1 unit in the FWS. An improvement of at least one score was seen in 69% of subjects on overall facial wrinkles assessment.68% of users who achieved wrinkle reduction of 1 full scale unit maintained some wrinkle improvement for at least 3 months after users stopped using NIRA.

Safety
No unanticipated or severe adverse events were reported. Adverse events reported included skin warmth and stinging, dryness, and temporary skin color changes where skin became darker in color. These were not unexpected.

H) Consensus Standards
The NIRA Beauty Skincare Laser complies with the following standards:

- ETSI EN 300 440-2 v1.4.1 (2010-08): Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
- ETSI EN 301 489-1 v1.9.2 (2011-09) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- ETSI EN 301 489-3 v1.6.1 (2002-08) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and

services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

- IEC 60601-1-2:2007 (Third Edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- AAMI ANSI ES 60601-1:2005(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11: 2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60355-1: 2010 Household and similar electrical appliances - Safety - Part 1: General requirements
- IEC 60355-2-23:2008 Household and similar electrical appliances - Safety - Part 2-23: Particular requirements for appliances for skin or hair care
- IEC 60825-1: 2007 Safety of laser products - Part 1: Equipment classification and requirements
- ASTM D4169-14 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 62366 (First Edition) + A1:2014 Medical devices -- Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6: 2010 (Third Edition) +A1;2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- AAMI ANSI HE75: 2009/(R) 2013 Human factors engineering – Design of medical devices

Conclusion

The NIRA Laser is substantially equivalent to the predicate devices. Clinical data demonstrate that the NIRA Laser is safe and effective, and meets its indications for use.