February 8, 2023

Dermal Photonics Corp
Felix Feldchtein
Vice President
153 Andover St, Ste 111
Danvers, Massachusetts 01923

Re: K222685
Trade/Device Name: NIRA Model 2
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: December 5, 2022
Received: December 6, 2022

Dear Felix Feldchtein:

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/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 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 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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K222685

Device Name
NIRA Model 2

Indications for Use *(Describe)*
The NIRA Model 2 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.

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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 153 Andover St Danvers, MA 01923
Official Contact:	David Bean CEO and President
B) Classification Names:	Light Based Over-The-Counter Wrinkle Reduction
Proprietary Name:	NIRA Model 2
Device Class:	Class II
Regulations	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	OHS
Classification panel:	General & Plastic Surgery
C) Predicate:	K163137 NIRA Beauty Skincare Laser
D) Date Prepared:	August 30, 2022

E) Device Description:
The NIRA Model 2 is a hand-held reusable OTC non-fractional diode laser device employing 1450 nm wavelength. The NIRA Laser consists of a handheld piece and USB charging cable. The handheld fits in the hand and the laser light comes out of the tip. There is a single USB C connector for battery charging.

F) Intended Use/Indications For Use:
The NIRA Model 2 is indicated for the treatment of periorbital wrinkles.

G) Substantial Equivalence Comparison and Discussion

Specifications			
	NIRA Model 2	**Predicate K163137 NIRA Skin (Model 1)**	**Comparison**
Spot size	12.5 x 13.8 mm^2	4x4 mm^2	Different
Light source	Non-fractional diode laser	Non-fractional diode laser	Same
Wavelength	1450 ±20 nm	1450 ±20 nm	Same
Pulse	2.0-3.1 sec pulse train	0.8 sec pulse train	Different
Laser max power	2 W	2 W	Same
Laser energy density (fluence)	2.1, 2.4, 2.7, 3.2 and 3.8 J/cm^2	2.16, 2.32, 2.48, 2.66, 2.97 J/cm^2	Different
Laser cooling	Forced Convection w/ fan	Natural Convection	SE
Laser fire start	Contact sensor, auto-trigger when all capacitive sensors engaged on skin	Contact sensor+Trigger button	SE
OTC home use	Yes	Yes	Same
Treatment schedule	Once or twice per day	Once or twice per day	Same
Weight	5 oz	5 oz	Same
Size	6.7 x 2.6 x 1.6 inches	6.7 x 2.4 x 1.6 inches	SE
Electrical, EMC requirements	Yes	Yes	Same
Laser, FCC requirements	Yes	Yes	Same
Usability requirements	Yes	Yes	Same

Similarities
The NIRA Model 2 has the same indications for use, is an OTC device and uses the same wavelength as the predicate device.
Like the predicate device, the NIRA Model 2 meets electrical safety, EMC, usability engineering, laser safety, and FCC regulations requirements.

Differences
Differences between the NIRA Model 2 and the predicate device include (see the table for details):

- Pulse duration
- Beam size
- Laser fire start
- Laser engine cooling

Despite the differences noted above both devices have very similar laser fluence (energy density) and intracutaneous temperature elevation and therefore produce very similar biological effect on the skin tissue.

Conclusion
Differences between the NIRA Model 2 and the predicate device do not raise issues of safety or effectiveness. The NIRA Model 2 is substantially equivalent to the predicate device.

H) 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 electrical safety, EMC, usability engineering, laser safety, and FCC regulations 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 lay person 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

Safety and clinical efficacy of the predicate device was assessed in human clinical trial performed in 2016. Since the Model 2 has substantially equivalent intracutaneous temperature elevation for very similar time, no separate clinical trial was performed for the Model 2.

I) Recognized Consensus Standards

The Dermal Photonics NIRA Model 2 complies with the following standards:

- IEC 60601-1-2:2014 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: 2015 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 60825-1: 2014 Safety of laser products - Part 1: Equipment classification and requirements
    - In lieu of compliance with 21 CFR 1040.10 and 21 CFR 1040.11 per FDA laser notice #56.
- IEC 62366:2015 Medical devices -- Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6: 2010 +A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Conclusion

The NIRA Laser is substantially equivalent to the predicate devices.