June 3, 2022

Paradigm Medical Corporation
% Maureen O'connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K213332
Trade/Device Name: Multifrax Laser System
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: ONG
Dated: May 6, 2022
Received: May 9, 2022

Dear Maureen O'connell:

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,

Purva Pandya, D.Eng.
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)*
K213332

Device Name
Multifrax Laser System

Indications for Use *(Describe)*
1550 nm: The Multifrax 1550 nm laser is indicated for use in dermatological procedures requiring coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Multifrax 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephiledes (freckles).

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.

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510(k) SUMMARY

Paradigm Medical Corporation
Multifrax Laser System
K213332

510(k) Owner
Paradigm Medical
7371 Los Brazos
San Diego, CA 92127

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: June 3, 2022

Trade Name of Device
Multifrax Laser System

Common or Usual Name
Powered laser surgical instrument with microbeam/fractional output

Classification Name
Laser surgical instrument for use in general and plastic surgery and dermatology;
21 C.F.R. §878.4810
Class II
Product Code: ONG

Predicate Device
Solta Medical, Inc. Fraxel Dual 1550/1927 Laser System cleared in K130193

Device Description
The Multifrax Laser System provides non-ablative fractional treatment using the 1550 nm and 1927 nm wavelengths. The mode of action is delivering a series of light pulses in a row as the handpiece tip is moved across the skin which leaves a pattern of microdots (Micro Thermal Zone (MTZ)) of irradiated skin.

Multifrax Laser System is a dual-wavelength diode laser system comprising two laser sources emitting at 1550 and 1927 nm and generating fine pulses of energy.

- Multifrax is a non-ablative and non-invasive fractional laser device.

- Multifrax is a light portable laser combining a small laser unit and 2 long lasting rechargeable batteries equipped with a belt clip.
- Multifrax offers optimized technical characteristics: adjustable treatment width, adjustable distance between laser pulses, distal tip with integrated high-performance movement and skin contact tracking sensors, and color touch screen display.

Indications for Use
1550 nm: The Multifrax 1550 nm laser is indicated for use in dermatological procedures requiring coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Multifrax 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephiledes (freckles).

Substantial Equivalence
Paradigm Medical believes that the Multifrax described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device which is the Fraxel Dual 1550/1927 nm Laser System cleared in K130193. The table below compares the properties of the two devices.

Characteristic	Multifrax	Fraxel Dual 1550/1927 nm Laser System
Manufacturer	Paradigm Medical	Solta Medical, Inc.
510(k) Number	-	K130193
Product Code	ONG	GEX
Regulation	21 CFR 878.4810	21 CFR 878.4810
Indications for Use	1550 nm: The Multifrax 1550 nm laser is indicated for use in dermatological procedures requiring coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars. 1927 nm: The Multifrax 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to	1550: The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars. 1927 nm: The Fraxel 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots),

	lentigos (age spots), solar lentigos (sun spots) and ephiledes (freckles).	solar lentigos (sun spots) and ephiledes (freckles).
Clearance Type	Prescription	Prescription
User	Healthcare Professional	Healthcare Professional
Operating Principles	Non-ablative treatment	Non-ablative treatment
Laser Source	Laser diode	Erbium fiber Thulium fiber
Delivery System	Handpiece	Fiber delivery to Handpiece
Laser Wavelength	1550 nm 1927 nm	1550 nm 1927 nm
Pulse Energy	1 to 70 mJ (1550 nm) 1 to 20 mJ (1927 nm)	4 to 70 mJ (1550 nm) 5 to 20 mJ (1927 nm)
Tissue Contact	Disposable contact tip	Disposable contact tips
Power source	2 rechargeable batteries	Power supply

The intended use of the Multifrax as well as the indications for use are identical. Both are prescription devices for use by trained healthcare professionals for non-ablative dermatological laser treatment. The devices have the same technological characteristics. Both lasers are 1550 nm and 1927 nm diode lasers. Both are delivered to the patient via a handpiece with a contact tip. The upper pulse energy of both devices is the same for both wavelengths. The scanning shape is a single line for both devices. Neither device has an aiming beam. Both devices are software controlled and operated via a touchscreen.

Performance Data

Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device. Testing was performed to the following standards and the Multifrax Laser System was found to meet the requirements:

- Electrical safety per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- Electromagnetic compatibility per IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Usability per IEC 60601-1-6 2010, AMD 1: 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Usability
- Laser equipment safety per IEC 60601-2-22 Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- Laser safety per IEC 60825-1:2014 Safety of laser products-Part 1: Equipment classification and requirements

- Software validation and verification per IEC 62304:2006 Medical device software-Software life cycle processes
- Biocompatibility per ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation; ISO 10993-10:2021 Biological evaluation of medical devices-Part 10 :Tests for irritation and skin sensitization; and ISO 10993-5 :2009 Third edition Biological evaluation of medical devices-Part 5 : Tests for in vitro cytotoxicity

Conclusion

Based on the substantial equivalence discussion and the performance testing, the Multifrax Laser System is substantially equivalent to the Fraxel Dual 1550/1927 nm Laser System.