Acclaro Corporation
Shlomo Assa
President
333 George Washington Highway
Smithfield, Rhode Island 02865

Re: K233803
Trade/Device Name: UltraClear Fractional 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: GEX
Dated: November 29, 2023
Received: November 29, 2023

Dear Shlomo Assa:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S

Digitally signed by Tanisha L. Hithe -S
Date: 2024.05.08 15:28:53 -04'00'

Tanisha Hithe
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)*
K233803

Device Name
UltraClear Fractional Laser System

Indications for Use *(Describe)*
The UltraClear Fractional Laser System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytids, furrows, fine lines, textural irregularities, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), benign pigmented lesions, and vascular dyschromia.

Fractional Effects:
The UltraClear Fractional Laser System with its accessories when used in Ultra mode is intended to produce fractional effects during skin resurfacing

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."

510(k) Summary
UltraClear Fractional Laser System
K233803

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Owner/Applicant:	Acclaro Corporation 333 George Washington Highway Smithfield, RI 02917
Official Correspondent	Shlomo Assa, President 333 George Washington Highway Smithfield, RI 02917 619-988-4796 sassa@acclaromd.com
Date of Summary:	May 7, 2024
Device Trade Name:	UltraClear Fractional Laser System
Common or Usual Name:	2910 nm laser system
Regulation Number:	21 CFR 878.4810
Device Class:	II
Product Code:	GEX
Panel:	General and Plastic Surgery
Predicate Device:	Joule Profractional System K173285
Reference Device:	UltraClear Fractional Laser System K210847
Device Description:	UltraClear Fractional Laser System is a transportable device. The system includes the 15" touch screen, on/off switch, foot peddle, an emergency stop button, remote interlock, and calibration port. The device console houses most of the power consuming components, including the laser module, medical grade power supply, the scanner drivers, software, TEC cooling module, water pump, fans, software controls, and all other electrical control components. The laser energy is delivered during treatment via the handpiece. A 635 nm visible red laser diode aiming beam is used to visualize the location of the beam during laser treatment.

Indications for Use:	The UltraClear Fractional Laser System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytids, furrows, fine lines, textural irregularities, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), benign pigmented lesions, and vascular dyschromia. Fractional Effects: The UltraClear Fractional Laser System with its accessories when used in Ultra mode is intended to produce fractional effects during skin resurfacing.

Technological Comparison to the predicate and reference devices

Device & Predicate Device(s):	K233803 (Subject Device)	K173285 (Predicate)	K210847 (Reference)
Light Source	Diode, Er:YAG	Er:YAG	Diode, Er:YAG
Wavelength (nm)	2910	2940	2910
Modes	CW, pulsed	Pulsed	CW, pulsed
Laser power (W)	10W	30W	10W
Energy/pulse/µbeam (mJ/pulse/µbeam)	0.6-1.5 (Clear Mode) 1.5-3.0 (Silk Mode) 3.6-30.0 (Ultra Mode) 0.6-1.5, 3.6-30.0 (UltraClear-Mode)	≤ 70 mJ	0.6-1.5 (Clear Mode) 1.5-3.0 (Silk Mode) 3.6-30.0 (Ultra Mode) 0.6-1.5, 3.6-30.0 (UltraClear-Mode)
µbeam dia. (µm)	170	450	170
Fluence per u-beam (J/cm^2)	15.9-132.2	~3.0	15.9-132.2
No. of circles in a spot of 10x10mm	49-81 rings (clear) 36-64 rings (silk)	-	49-81 rings (clear) 36-64 rings (silk)
Inter µbeam spacing (mm) (In Ultra mode for subject device) Inter ring spacing (mm) (in clear and ultra mode)	1.25-0.7 (1.5%-5%, Ultra) 1.25-1.66 (30-50%, Clear) 1.43-2.0 (20-40%,	-	1.25-0.7 (1.5%-5%, Ultra) 1.25-1.66 (30-50%, Clear) 1.43-2.0 (20-40%,

Device & Predicate Device(s):	K233803 (Subject Device)	K173285 (Predicate)	K210847 (Reference)
	Silk)		Silk)
µbeam density or coverage (in a circle or spot)	30-50% (Clear mode) 20-40% (Silk mode) 1.5-5% (Ultra mode) 30-50% (UltraClear mode)	-	30-50% (Clear mode) 20-40% (Silk mode) 1.5-5% (Ultra mode) 30-50% (UltraClear mode)
Spot size (mm X mm)	2X2 – 15X15	1.3X1.3 – 20X20	2X2 – 15X15
Spot size patterns	Same as above	Same as above	Same as above
Repetition Rate (Hz)	3	3	3
Pulse duration (ms)	0.1-3.0	0.5-1.5	0.1-3.0
Aiming beam	Yes, 650 nm	Yes, red/green	Yes, 650 nm
Diode Cooling	Water to air heat exchanger	Water to air heat exchanger	Water to air heat exchanger
Skin Cooling	No	No	No

Technological Characteristics / Substantial Equivalence

The UltraClear Fractional Laser System is substantially equivalent in design, function, operating principles, and intended use to the Joule ProFractional System (K173285) predicate device, based on the information presented. The devices share the same design and technical features, which includes calibration port, handpiece, similar wavelength, laser medium, fiber delivery, power supply, internal cooling system, hardware, electronics, firmware, software and user display screen.

Both the new device and predicate device share the same laser operating principles, such as energy, pulse width, repetition rate, fractional delivery and offers a range of spot sizes. Any minor design differences do not raise any new types of safety or effectiveness questions, thus rendering substantial equivalence.

Performance Data

Acclaro Corporation conducted non-clinical performance studies to confirm the overall functional specification testing of the UltraClear Fractional Laser System against its design specifications and intended use.

The following testing was conducted in support substantial equivalence.

Biocompatibility Testing

Testing was conducted in accordance with ISO-10993-1 to demonstrate the patient contacting material of the handpiece is safe for transient use (≤24 hours of contacting).

Electromagnetic Compatibility & Electrical Safety

UltraClear Fractional Laser System underwent electrical safety and electromagnetic compatibility with passing results according to the following recognized standards.

- IEC 60825-1, 2007: Safety of Laser Products – Part 1: Equipment classification and requirements.
- IEC 60601-1, 2005+A1:2012: Medical electrical equipment-- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Ed. 3, 2007-03: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-2-22 Third Edition, 2007-05: Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

UltraClear Fractional Laser System underwent software verification and validation testing, which demonstrated the software is appropriate for release and that the system performed as intended. Furthermore, the testing verified the energy outputs of the system meet its design specifications.

Conclusion

The UltraClear Fractional Laser System has the same Intended Use/Indications for Use as the predicate device. The minor differences between the two devices do not raise new or different questions about safety and effectiveness. The performance data presented in this 510(k) Premarket Notification support the safety of the new device. Additionally, the data further supports the new device should perform as intended and to its specifications. In sum, the UltraClear Fractional Laser System is as safe and effective as its predicate device.