December 10, 2021

FA International, LP
℅ Sharon Timberlake
Regulatory Consultant
Sharon Timberlake Consulting, LLC
27 Dunelm Road
Bedford, Massachusetts 01730

Re: K210847
Trade/Device Name: UltraClear 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, ONG
Dated: May 9, 2021
Received: May 11, 2021

Dear Sharon Timberlake:

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
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)*

K210847

Device Name
UltraClear Laser System

Indications for Use *(Describe)*

The UltraClear Laser System is intended for use in Dermatology and Plastic Surgery applications for the following indications for use:

General skin resurfacing procedures

Ultra mode is further indicated for the following fractional applications: Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

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.

K210847

510(k) Summary
UltraClear Laser System

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

Owner/Applicant:	**FA International, LP** 614 George Washington Highway Lincoln, RI 02865 (619) 988-4796
Official Correspondent	**Sharon Timberlake Consulting, LLC** Sharon Timberlake, MSHS, RAC, CCRA 27 Dunelm Road Bedford, MA 01730 (617) 957-1434
Date of Summary:	December 8, 2021
Device Trade Name:	UltraClear Laser System
Common/Usual Name:	2910 nm laser system
Regulation Number:	21 CFR 878.4810
Device Class:	II
Product Code:	GEX/ONG
Panel:	General and Plastic Surgery
Predicate Devices	Joule ProFractional System (K180508)
Reference Device	CO_2RE System (K181523)
Device Description:	UltraClear 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 system is a fiber laser device operating at a wavelength of 2,910nm. The system incorporates a fiber couple laser diode assembly pumping erbium doped fluoride glass fiber to generate laser emission. 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 Laser System is intended for use in Dermatology and Plastic Surgery applications for the following indications for use: General skin resurfacing procedures. Ultra mode is further indicated for the following fractional applications: Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

Predicate Comparison Table

Specifications	UltraClear Fractional Laser System	JOULE ProFractional System	Substantial Equivalence Assessment
Manufacturer	FA International	Sciton, Inc.	Not Applicable
K Number	K210847	K180508	Not Applicable
Product Code	GEX, ONG	GEX, ONG	Same
Prescription Use	Yes	Yes	Same
Laser Energy Source	Er: YAG	Er: YAG	Same
Laser Delivery	Fiber & Handpiece	Fiber, Handpiece, Articulated arm	Substantially equivalent
Wavelength	2910 nm	2940 nm	Substantially equivalent
Aiming Beam	Red diode laser 5mW	Red diode laser 5mW	Same
Target Chromophore	Water	Water	Same
Fractional Technology	Yes	Yes	Same
Energy per Microbeam(mJ/mb)	0.6-1.5 (Clear Mode) 1.5-3.0 (Silk Mode) 3.6-35.0 (Ultra Mode) 0.6-1.5, 3.6-35.0 (UltraClear-Mode)	Up to 70	Similar, within range
Adjustable Spot Size	2x2mm - 15x15mm	1.3x1.3mm - 20x20mm	Substantially equivalent
Pulse/Repetition Rate	Up to 3 Hz	Up to 3 Hz	Same
Pulse Width/Duration	0.1 to 3.0 msec (or 3000 µsec)	0.5 to 1.5 msec (or 1500 µsec)	Substantially equivalent
Delivery System	Fiber optic arm with handpiece	Articulated arm and/or fiber optic arm with handpiece	Same

Cooling System	Water & Air	Water & Air	Same
Electrical Requirements	100-240 VAC/8.5A, 50/60 Hz	230 VAC/25A, 50/60 Hz	Substantially equivalent
Software/GUI/ Touch Screen	Yes	Yes	Same
Energy Monitor	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Same
Console Dimensions	w15.9" x d20.5" x h42.1"	w14" x d21" x h41"	Substantially equivalent
Weight	80 Lbs	200 Lbs	Substantially equivalent
Power Supply	Yes	Yes	Same

Technological Characteristics / Substantial Equivalence

The UltraClear Laser System is substantially equivalent in design, function, operating principles, and intended use to the Joule ProFractional System (K180508) 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, energy 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

FA International, LP conducted performance studies to confirm the overall functional specification testing of the UltraClear Laser System against its design specifications and intended use. The following testing was conducted in support substantial equivalence.

<u>Histology Study</u>
Human biopsies were taken and analyzed post laser treatment. Tissue samples were taken from three participants to establish the thermal damage and tissue effect of lasing.

<u>Biocompatibility</u>
The patient contacting material of the handpiece are identical to the reference device.

Electromagnetic Compatibility & Electrical Safety

UltraClear 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 Edition 4.0 2014-02: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-2-22:2007 + A1: 2012, Edition 3.1: Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

Software Validation and Verification Testing

UltraClear 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 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 Laser System is as safe and effective as its predicate device.