April 13, 2021

AVAVA, Inc.
Lewis Levine
Executive Director, Engineering
275 Second Avenue, Floor 3
Waltham, Massachusetts 02451

Re: K202884
Trade/Device Name: SR-1 Skin Treatment 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: September 25, 2020
Received: September 28, 2020

Dear Lewis Levine:

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 U. Pandya -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202884

Device Name
SR-1 Skin Treatment System

Indications for Use *(Describe)*
The SR-1 Skin Treatment System is indicated for use in dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

The SR-1 Skin Treatment System is intended to be used by medical professionals and staff who are trained in the use of lasers and who are familiar with the technology, operation of the system, and safety precautions.

The SR-1 Skin Treatment System is a prescription device. Federal law restricts this device to sale by or on the order of a physician or any practitioner licensed by state law to use or order the use of this device.

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

General Provisions

510(k) Owner's Name:	AVAVA, Inc.
Address:	245 Second Avenue, Floor 3 Waltham, MA 02451 USA
Contact Person:	Lewis Levine Executive Director-Engineering
Phone Number:	Office: (857) 305-9604, Cell: (617) 510-2103
Fax Number:	Not Applicable
Classification Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and Dermatology
Regulation:	21 CFR § 878.4810
Regulatory Class:	II
Product Code:	ONG
Proprietary Name:	SR-1 Skin Treatment System
Common Name:	Powered Laser Surgical Instrument with Microbeam/Fractional Output
Date Summary Prepared:	September 25, 2020

Name of Predicate Device(s)

- Fraxel® DUAL 1550/1927: K130193, K060310
- Lumenis® Stellar M22™: K193500, K130028

Intended Use

The SR-1 Skin Treatment System is indicated for use in dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

The SR-1 Skin Treatment System is intended to be used by medical professionals and staff who are trained in the use of lasers and who are familiar with the technology, operation of the system, and safety precautions.

Device Description

The SR-1 Skin Treatment System is a 1550nm-based laser system intended to generate thermal zones of damage in skin. The system includes three (3) main components: Console, Tablet, and Patient Interface. The Console houses the system control electronics, power distribution, contact cooling, and laser. The Tablet is the primary user interface for controlling the system through a touch screen graphical user interface. The Patient Interface contains the optics, scanner, laser aperture, and contact cooling interface.

The SR-1 Skin Treatment System is a software-controlled device. The operator enters treatment parameters on the Tablet and places the Patient Interface on the treatment site. A treatment is initiated by the operator to cause laser energy to be projected into the skin of a patient. The device is intended to be used by a suitably trained professional in a clinical setting. There are no sterile components.

Technological Characteristics

The SR-1 Skin Treatment System has the same intended use and similar indications for use, technological characteristics and operating principles as the 1550 module of the Fraxel DUAL and the ResurFX module of the Lumenis Stellar M22. The design and components are very similar to the predicate devices as shown in the following table. The differences are minor and do not raise any new issues of safety or efficacy of the SR-1 Skin Treatment System device as shown in the performance testing results.

Table 8-1. Device Comparison

	Proposed SR-1 Skin Treatment System	**Predicate device Fraxel DUAL 1550 module (K130193)**	**Predicate device Lumenis Stellar M22 ResurFX module (K193500)**
Intended Use	The SR-1 Skin Treatment System is indicated for use in dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.	The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for the treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actnic keratosis, and melasma, and for the treatment or periorbital	Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

		wrinkles, acne scars and surgical scars.	
Operating Principals	Scanned pulsed 1550nm laser energy directed into the skin via an operator controlled delivery system.	Scanned pulsed 1550nm laser energy directed into the skin via an operator controlled delivery system.	Scanned pulsed 1550nm laser energy directed into the skin via an operator controlled delivery system.
Laser Source	1550nm erbium glass diode pumped fiber laser	1550nm erbium glass diode pumped fiber laser	1565nm erbium glass diode pumped fiber laser
Output power	20W	30W	15W
Maximum pulse energy	70 mJ	70 mJ	70 mJ
Maximum pulse width	10 ms	10 ms	10 ms
Tissue contact	Reusable sapphire cooled tip	Disposable contact tips	Reusable sapphire cooled tip
Cooling mechanism	Continuous contact cooling	Air cooling	Continuous contact cooling
Software control	Yes	Yes	Yes
User interface	Touchscreen	Touchscreen	Touchscreen

Risk Analysis

Risk analysis was performed according to IEC 14971:2007 Medical Devices- Application of Risk Management to Medical Devices, reviewed by a nationally recognized testing laboratory (NRTL), and found to be in compliance.

Summary of Performance Testing

Electrical Safety, Electromagnetic Compatibility, Usability, Biocompatibility and Laser Safety

Evaluation of the device was conducted by a nationally recognized testing laboratory (NRTL) and was found in compliance with the following standards:

- IEC 60601-1-2:2014 Ed 4.0 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 62304:2006 + A1:2015, Ed. 1.0 Medical device software - Software life cycle processes

- IEC 60601-1-6:2010, AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62366-1: 2015 Medical devices - Part 1: Application of usability engineering to medical devices

- IEC 60601-2-22: 2007 (Third Edition) + A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Non-Clinical Performance Data

The SR-1 Skin Treatment System performance characteristics have been evaluated through usability testing compliant to FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices (2016)* and IEC 62366-1 and verification and validation of the SR-1 Skin Treatment System's laser energy, performance and control mechanisms. The performance of the SR-1 Skin Treatment System and related parameters of the predicate device are substantially equivalent.

A 14 day in vivo human study assessing safety, healing and MTZ morphology was performed in 14 healthy subjects using a power range of 20 - 70mJ. The resulting zones of thermal damage and the healing rate were determined, through histological analysis, to be comparable to the predicate Fraxel DUAL 1550 module.

Software verification and validation testing was conducted, and documentation provided as recommended by FDA Guidance *Content of Premarket Submissions for Software Contained in Medical Devices (2005)* and IEC 62304. Device software verification and validation results were found acceptable for software release.

Biocompatibility of the patient contacting materials was established per FDA Guidance *Use of International Standard ISO 10993-1 Biological evaluation of medical devices –Part 1: Evaluation and Testing Within a Risk Management Process (2018)* and the referenced standard.

Clinical Performance Data

Clinical trials were not deemed necessary as the device is using the same key technology, operating principles, and intended use as the predicate devices.

Summary of Substantial Equivalence

The SR-1 Skin Treatment System and the predicate devices have the same intended use. The SR-1 Skin Treatment System presents similar technological characteristics as its predicate devices, including the laser type, wavelength, and device design. Although there are minor differences in the details of the device design, they are not sufficient to raise new questions of safety or efficacy.

Conclusion

The SR-1 Skin Treatment System is substantially equivalent to the Fraxel DUAL 1550/1927 and the ResurFX module of the Lumenis Stellar M22. The new device has similar intended use and indications for use, technological characteristics and the same principle of operation as the predicate device. The minor design differences raise no new issues of safety or efficacy as demonstrated by histological assessments. The histological data show that the SR-1 Skin Treatment System performs in accordance with its specifications and requirements.