November 21, 2022

AVAVA, Inc
Jay Bhawalkar
Chief Technology Officer
275 Second Avenue, Floor 3
Waltham, Massachusetts 02451

Re: K221268
Trade/Device Name: MIRIA 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: October 31, 2022
Received: October 31, 2022

Dear Jay Bhawalkar:

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,

Colin K. Chen -S

for

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)*
K221268

Device Name
MIRIA Skin Treatment System

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

The MIRIA 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 MIRIA 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 K221268

General Provisions

510(k) Owner's Name:	AVAVA, Inc.
Address:	275 Second Avenue, Floor 3 Waltham, MA 02451
Contact Person:	Jay Bhawalkar, PhD Chief Technology Officer
Phone Number:	Office: (617) 377-7945
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:	MIRIA Skin Treatment System
Common Name:	Powered Laser Surgical Instrument with Focal Point Technology
Date Summary Prepared:	October 28, 2022

Primary Predicate Device(s)

SR-1 Skin Treatment System: K202884

Device Description

The MIRIA Skin Treatment System falls under a class of intradermally focused lasers creating a targeted spatially selective conical lesion in the skin. This intradermal conical lesion profile distinguishes this class of lasers from those that generate a cylindrical column of injury. The ability of the beam to be focused to different depths is important for treatment of all skin tones and safety in the extended energy range in the MIRIA.

The MIRIA is a 1550nm-based laser system that 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 focusing optics, scanner, laser aperture, and contact cooling interface.

The MIRIA 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 suitably trained personnel in a professional setting. There are no sterile components.

Indications for Use

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Summary of Technological Similarities/Differences

The intended use, technological characteristics, and operating principles of the subject device and the predicate device are the same with the exception of the pulse energy range (and the corresponding pulse width), as shown in the following table. This differences do not raise different questions of safety or efficacy for the MIRIA Skin Treatment System as shown in the performance testing results.

Table 8-1. Device Comparison

	Subject Device (MIRIA Skin Treatment System)	**Predicate Device (SR-1 Skin Treatment System) K202884**
Operating principal	Scanned pulsed 1550nm laser energy focused into the skin via an operator-controlled delivery system.	Scanned pulsed 1550nm laser energy focused 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
Output power	20W	20W
Maximum pulse energy	150 mJ	70 mJ
Maximum pulse width	12 ms	10 ms
Tissue contact	Reusable sapphire cooled tip	Reusable sapphire cooled tip
Cooling mechanism	Continuous contact cooling	Continuous contact cooling
Software control	Yes	Yes
User interface	Touchscreen	Touchscreen

Performance Testing

The following verification methods were used to evaluate performance at the extended pulse energy range.

- Verification of the ability of the system to focus the energy to a depth of 0 to 1500 micrometers into the skin.
- Verification of energy delivery from 3 to 150 mJ.
- A healing study to demonstrate device performance for the creation of conical microscopic treatment zones (CTZs) and to demonstrate healing post-treatment using worst-case parameter combinations.
- Software verification and validation for those elements impacted by the change in the values for the pulse energy in according to the FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005) and IEC 62304:2006 +A1:2015, Ed. 1.0 Medical device software - Software life cycle processes

  Note: The software permits only certain combinations of microbeam energy and focus depth to be selected by the user.

Conclusion

The MIRIA Skin Treatment System has the same intended use, technological characteristics, and principle of operation as the predicate device. The expanded pulse energy range raised no different issues of safety or efficacy as demonstrated the performance data. The data show that the MIRIA Skin Treatment System performs in accordance with its specifications and requirements for both safety and effectiveness and does not raise concerns about the safety and efficacy of the device in comparison to the predicate. Thus, the MIRIA Skin Treatment System and the predicate device are substantially equivalent.