October 20, 2025

Avava Inc.
Richard Bankowski
Executive VP of Global Clinical and Regulatory
275 2nd Ave
3rd Floor
Waltham, Massachusetts 02451

Re: K252155
Trade/Device Name: AVAVA™ 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 12, 2025
Received: September 12, 2025

Dear Richard Bankowski:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.10.20 22:47:55 -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)*
K252155

Device Name
AVAVA™ Skin Treatment System

Indications for Use *(Describe)*
The AVAVA™ Skin Treatment System is indicated for use in the treatment of fine lines and wrinkles, the treatment of acne scars, and dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

The AVAVA™ 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 AVAVA™ 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.

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."

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K252155

General Provisions

510(k) Owner's Name:	AVAVA, Inc.
Address:	275 Second Avenue, Floor 3 Waltham, MA 02451
Contact Person:	Richard Bankowski EVP of Global Clinical and Regulatory
Number:	Office: (617) 912-2680
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:	AVAVA™ Skin Treatment System
Common Name:	Powered Laser Surgical Instrument with Microbeam/ Fractional Output
Date Summary Prepared:	October 15, 2025

Name of Predicate Device(s)

AVAVA™ Skin Treatment System (K250402)

Intended Use

The AVAVA™ Skin Treatment System is indicated for use in the treatment of fine lines and wrinkles, the treatment of acne scars, and dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

The AVAVA™ 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 AVAVA™ 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 AVAVA.

The AVAVA 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 AVAVA™ 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 system also has a USB port.

The device is intended to be used by suitably trained personnel in a professional setting. There are no sterile components.

Indications for Use

The AVAVA™ Skin Treatment System is indicated for use in the treatment of fine lines and wrinkles, the treatment of acne scars, and dermatologic procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures.

The AVAVA™ 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 AVAVA™ 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.

Summary of Technological Similarities/Differences

The subject device is identical to the predicate device in technical parameters and intended use. The difference between the subject and predicate device originates from the use of the subject device for the treatment of fine lines and wrinkles. Clinical data are provided to support the expanded indications for use.

Summary of Non-Clinical Testing

Not needed.

Summary of Clinical Testing

A retrospective clinical trial titled "AVAVA Retrospective Wrinkles" was conducted from initial approval on November 27, 2024 until database lock on June 5, 2025. Grading and analysis of data was completed after database lock and fully completed on June 13, 2025. The AVAVA laser is a 1550nm non-ablative fractional device which delivers energy in micro-pulses over a large area as the handpiece is scanned across the skin. Simultaneously, the sapphire cooled tip is applied to the skin to provide immediate pre- and post-pulse cooling for the patient to improve comfort and tolerability of the treatment.

Demographic, efficacy, and safety data were analyzed as a full data set due to the nature of the protocol as a retrospective review. Subjects were included if there were found to present with wrinkles at baseline imaging and were treated in the area of their wrinkles with the AVAVA laser.

The study initially analyzed data from 33 subjects of Fitzpatrick Skin Type I, II, III, IV, and VI who were enrolled and treated in a prior IRB-approved study and received a treatment in the area of their wrinkles which was then further refined to 28 subjects who attended a 3-month or later post-treatment follow-up. All 28 subjects were included as part of this retrospective review which included analysis of demographic data, treatment data, and side effects. Photographs were presented to a panel of evaluators who reported statistically significant improvement in Fitzpatrick Wrinkle and Elastosis Scale (FWES) scores ($p < 0.001$) and 75% of subjects were identified as responders exhibiting at least 1 point improvement on the 9-point FWES in at least 2 of 3 blinded reviewer scores. Treatment was well tolerated by all subjects and no unanticipated adverse events were noted. Overall the AVAVA Laser was found to be safe and effective for the treatment of fine lines and wrinkles in Fitzpatrick Skin Types I – VI.

Conclusion

The AVAVA Skin Treatment System has the same intended use, technological characteristics, and principle of operation as the predicate device. The clinical study conducted to support the new indication for use of the treatment of fine lines and wrinkles showed that the device is both effective and safe to use on Fitzpatrick Skin Types I – VI. Thus, the modified AVAVA Skin Treatment System and the predicate device are substantially equivalent.