June 28, 2022

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

Re: K213726
Trade/Device Name: PL-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: GEX, ONG
Dated: May 25, 2022
Received: May 27, 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,

Jianting Wang, Ph.D.
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)*
K213726

Device Name
PL-1 Skin Treatment System

Indications for Use *(Describe)*
The PL-1 Skin Treatment System is a 1064 nm laser system intended to ablate, vaporize, and coagulate soft body tissues for aesthetic and cosmetic applications in the medical specialties of dermatology and plastic surgery. It is also indicated for removal of benign pigmented lesions including; nevus of Ota, café au lait spot, ephelides, solar lentigo (lentigines), Becker's nevus, nevus spilus and treatment of common nevi..

The PL-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.

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 K213726

General Provisions

510(k) Owner's Name:	AVAVA, Inc.
Address:	245 Second Avenue, Floor 3 Waltham, MA 02451
Contact Person:	Jay Bhawalkar, Ph.D., Chief Technology Officer
Phone Number:	Office: 617-377-7961
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:	GEX, ONG
Proprietary Name:	PL-1 Skin Treatment System
Common Name:	Powered Laser Surgical Instrument with Microbeam Output
Date Summary Prepared:	May 26, 2022

Name of Predicate Device(s)

- Primary Predicate: Quanta Chrome, K202503

Intended Use

The PL-1 Skin Treatment System is a 1064 nm laser system intended to ablate, vaporize, and coagulate soft body tissues for aesthetic and cosmetic applications in the medical specialties of dermatology and plastic surgery. It is also indicated for removal of benign pigmented lesions including; nevus of Ota, café au lait spot, ephelides, solar lentigo (lentigines), Becker's nevus, nevus spilus and treatment of common nevi. The PL-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 PL-1 Skin Treatment System is a 1064nm, Q-switched laser system. The system includes three (3) main components: Console, Tablet, and Handpiece. 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 Handpiece contains the optics, focusing components, and reference window assembly.

The PL-1 Skin Treatment System is a software-controlled device. The operator enters treatment parameters on the Tablet and places the Handpiece 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 PL-1 Skin Treatment System has the same intended use and similar indications for use, technological characteristics and operating principles as the Quanta Chrome system (Quanta systems) operating in the 1064 Q-switched, nanosecond mode with a microbeam handpiece. The design and components are very similar to the Quanta system as shown in the following table. The differences are minor and do not raise any new issues of safety or efficacy of the PL-1 Skin Treatment System device as shown in the performance testing results.

Characteristic	Subject Device	Primary Predicate	Substantial Equivalence?
Device	PL-1 Skin Treatment System	Chrome	NA
Manufacturer	AVAVA	Quanta	NA
510k	K213726	K202503	NA
Classification	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	Yes, same classification
Product code	GEX, ONG	GEX	Yes, same code
Device class	II	II	Yes, same class
Intended use	Aesthetic and cosmetic applications requiring ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology and plastic surgery	Aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery	Yes, same intended use for aesthetic and cosmetic applications
Indications	The PL-1 Skin Treatment system is indicated for the removal of benign pigmented lesions including; nevus of Ota, café au lait spot, ephelides, solar lentigo (lentigines), Becker's nevus, nevus spilus, and treatment of common nevi.	The Quanta Chrome system operating in 1064nm nanosecond mode with microbeam handpiece is indicated for: Removal of dark ink (black, blue and brown) tattoos. Removal of benign pigmented lesions including; nevus of Ota, Café au lait spot, Ephalides, solar lentigo (lentigines), Becker Nevus, Nevus spilus. Treatment of common nevi. Removal or lightening of unwanted hair Skin resurfacing procedures for the treatment of acne scars and wrinkles.	Yes, same indication for use for BPL based on equivalence in operating principle, laser type, wavelength, treatment parameters and demonstrated performance to specifications

Characteristic	Subject Device	Primary Predicate	Substantial Equivalence?
Operating Principles			
Focused microbeams	Yes	Yes	Yes
Mechanism	Selective photothermolysis	Selective photothermolysis	Yes
Laser			
CDRH Laser Classification	Class 4	Class 4	Yes
Q-switched flash lamp pumped laser	Yes	Yes	Yes
Wavelength (nm)	1064	1064	Yes
Maximum pulse energy (mJ)	850	800	Yes, difference of 6% is well under acceptable tolerance of 20% for single system per IEC 60601-2-22
Nominal pulse width (ns)	6 to 12	6 to 12	Yes
Pulse repetition rate, maximum (Hz)	10	20	Yes , repetition rate for the subject device is a subset of the cleared specification for the predicate device
Aiming beam	None	**635 nm**	Yes, position at intended treatment site achieved through specified means.
Treatment			
Optics	Focusing optics in handpiece	Focusing optics in handpiece	Yes, similar delivery of focused laser energy
Tissue contact	Reference window	Distance gauge	Yes, treatment distance is maintained through specified means
Cooling mechanism	None	Integrated skin cooler for optional use prior to laser treatment	Yes, optional for predicate system.
Energy delivery	Microbeam	Microbeam	Yes
Number of microbeams	60	66	Yes, similar number of microbeams covering same spot dimension
Spot diameter (mm)	8 mm round	8 mm round	Yes
Max fluence per microbeam (J/cm^2)	Up to 45	Up to 44	Yes
Output verification	Bench testing	Bench testing	Yes
Device Characteristics			
User interface	Touchscreen	Touchscreen	Yes

Characteristic	Subject Device	Primary Predicate	Substantial Equivalence?
Software Control	Yes	Yes	Yes
Laser trigger	Foot switch	Foot switch	Yes
Emergency shut-off	Yes	Yes	Yes
Safety			
FDA CDRH 21 CFR 1040	Yes	Yes	Yes
Electrical safety (IEC 60601-1)	Yes	Yes	Yes
Electromagnetic compatibility (IEC 60601-1-2)	Yes	Yes	Yes

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: 2019 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 PL-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 PL-1 Skin Treatment System's laser energy, performance and control mechanisms. The performance of the PL-1 Skin Treatment System and related parameters of the predicate devices are substantially equivalent.

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.

Animal studies and clinical performance testing were not deemed necessary as the device is using the same key technology, operating principles, and intended use as the predicate device.

Summary of Substantial Equivalence

The PL-1 Skin Treatment System and the predicate devices have the same intended use for the 1064 Q-switched nanosecond mode with microbeam handpiece. The PL-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 PL-1 Skin Treatment System is as safe and effective as the predicate devices operating in the 1064 Q-switched nanosecond mode with a microbeam handpiece. The new device has similar intended use and indications for use, technological characteristics and the same principle of operation as the predicate devices. The minor design differences raise no new issues of safety or efficacy as demonstrated by the performance data. The data show that the PL-1 Skin Treatment System performs in accordance with its specifications and requirements for both safety and effectiveness in similarity to the predicate devices. Thus, the PL-1 Skin Treatment System and the predicates are substantially equivalent.