November 30, 2020

Avenda Health, Inc.
% Michael Billig
Co-Founder and Chief Executive Officer
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K201687
Trade/Device Name: Avenda Health 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
Dated: June 19, 2020
Received: June 22, 2020

Dear Michael Billig:

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 and Part 809); 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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201687

Device Name
Avenda Health Treatment System

Indications for Use *(Describe)*

The Avenda Health Treatment System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 980nm.

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

510(k) Notification K201687

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Santa Monica, CA 90401
USA
Phone: 310-957-5202

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Application Correspondent:

Michael J. Billig
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USA
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Email: mjb@experiengroup.com

Date Prepared: November 23, 2020

DEVICE INFORMATION [807.92(a)(2)]

Trade Name: Avenda Health Treatment System

Generic Name: Powered Laser Surgical Instrument

Common Name: Focal Laser Therapy System

Classification: 21 CFR§878.4810, Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology

Product Code: GEX

Regulatory Class: II

510(k) SUMMARY

PREDICATE DEVICE [807.92(a)(3)]

Predicate Device: Clinical Laserthermia Systems AB Tranberg^{CLS} Thermal Therapy System (K142216)

Reference Predicate Device: Medtronic Navigation Inc. Visualase Thermal Therapy System (K181859)

DEVICE DESCRIPTION [807.92(a)(4)]

The Avenda Health Treatment System ("Treatment System") is a thermal laser ablation system that causes coagulation necrosis of soft tissue. The Treatment System consists of the capital system Workstation and the single use Laser Applicator Kit. The Workstation contains core system hardware and software, provides the System's touchscreen user interface (UI), and serves as a "hub" to facilitate the connectivity of other System components. The Laser Applicator Kit consists of two patient-contacting disposable components, the Laser Catheter, and the Thermal-Optical Probe ("TOP"), which facilitate delivery of laser energy and monitoring of temperature, respectively. The Treatment Monitoring Software, which operates on the Workstation, provides the UI for controlling the device, displays previously generated patient and treatment plan information for the procedure, and actively monitors the treatment progress during a procedure by displaying output from the TOP.

The Treatment System is additionally used with an off-the-shelf accessory, the Tubing Set, which transports saline in a closed-loop system between the Workstation and Laser Catheter to provide cooling of the Laser Catheter. The Treatment System further includes an optional patient-contacting disposable accessory, the Multi-Channel Needle Guide ("MCG"), which may be used to attach an ultrasound probe to the Laser Catheter and TOP for enhanced visualization tracking, if desired.

INDICATIONS FOR USE [807.92(a)(5)]

The Avenda Health Treatment System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 980nm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [807.92(a)(6)]

The proposed device has the same intended use as the predicate device and reference predicate device. All three devices are powered surgical laser systems, used in a similar range of surgical applications, which perform coagulation of soft tissue at comparable power and wavelengths that can be conducted under image visualization and guidance. The devices are furthermore similar in technological characteristics with respect to providing a similar range of tissue damage and thermal monitoring capabilities. While there are minor technological differences between the

510(k) SUMMARY

proposed and predicate device, particularly with respect to specific laser parameters, these differences do not raise any different questions of safety and effectiveness, as confirmed through the results of performance testing.

The following table (Table 1) presents a tabular comparison of technological characteristics between the proposed device, predicate device, and reference predicate device.

Table 1: Substantial Equivalence Table

Feature	**Predicate Device**	**Reference Predicate Device**	**Proposed Device**
	Clinical Laserthermia Systems AB. Tranberg^{CLS} Thermal Therapy System (K142216)	**Medtronic Navigation Inc. Visualase Thermal Therapy System (K181859)**	**Avenda Health Inc. Avenda Health Treatment System (K_____)**
Classification	21 CFR§878.4810, Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	21 CFR§878.4810, Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	Same
Product Code	GEX	GEX, FRN, LLZ	GEX
Intended Use/Indications for Use	The Tranberg^{CLS} Thermal Therapy System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery.	The Visualase™ Thermal Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI	The Avenda Health Treatment System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 980nm.

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Feature	Predicate Device	Reference Predicate Device	Proposed Device
	Clinical Laserthermia Systems AB. Tranberg^{CLS} Thermal Therapy System (K142216)	**Medtronic Navigation Inc. Visualase Thermal Therapy System (K181859)**	**Avenda Health Inc. Avenda Health Treatment System (K_____)**
		sequences is available, the Visualase™ system can process images using proton resonance-frequency (PRF) shift analysis and image subtraction to relate changes in complex phase angle back to relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time. The Visualase™ Thermal Therapy System is compatible with General Electric Medical Systems Signa model MR scanners and with Siemens Medical Solutions Magnetom Espree systems. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of Visualase™ analysis.	
Wavelength (Diode laser generator)	1064nm	800nm – 1064nm	980nm
Output power	1W - 25W at output port	3W – 15W at output port	Up to 14W at output port
Output power accuracy	±10% of selected value	±20% of selected value	±20% of selected value

510(k) SUMMARY

Feature	Predicate Device	Reference Predicate Device	Proposed Device
	Clinical Laserthermia Systems AB. Tranberg^{CLS} Thermal Therapy System (K142216)	**Medtronic Navigation Inc. Visualase Thermal Therapy System (K181859)**	**Avenda Health Inc. Avenda Health Treatment System (K_____)**
Mode of operation	Continuous wave (CW) or controlled by tissue temperature monitored by a temperature sensor	Continuous wave (CW), pulsed, or external modulation modes.	Continuous Wave (CW)
Output power increments	1W	0.5W	0.1W
Cooling	TEC	TEC	Same
Channel(s)	1	1	Same
Output port	SMA 905	SMA 905	Proprietary
Aiming wavelength	635nm	650nm	635 or 650nm
Laser Type (per IEC 60825-1)	Class 4	Class 4	Same
Laser Safety Classification FDA	Class 2	Class 2	Same
Power source (General)	100-240V AC / 50-60Hz	100-240V AC / 50-60Hz	120V AC / 60Hz
Operating temperature range	15ºC – 28ºC	18ºC – 35ºC	10ºC – 33ºC
Emergency switch	Yes	Yes	Same
Key activation of laser output	Yes	Yes	Same
Remote Interlock	Yes	Yes	Same
Power ON/OFF visual indicator	Yes	Yes	Same
Laser emission Indicator	Yes	Yes	Same
Internal laser power monitor	Yes	Yes	Same
Manual reset	Yes	Yes	Same
Fiber insertion interlock	Yes	Yes	Same
Audio warning signal level	Fixed at HIGH	HIGH, MEDIUM, LOW, and OFF	Same as Predicate Device
Pump-driven applicator cooling	Yes	Yes	Same

510(k) SUMMARY

Feature	Predicate Device	Reference Predicate Device	Proposed Device
	Clinical Laserthermia Systems AB. Tranberg^{CLS} Thermal Therapy System (K142216)	**Medtronic Navigation Inc. Visualase Thermal Therapy System (K181859)**	**Avenda Health Inc. Avenda Health Treatment System (K_____)**
Applicator Kit Included?	No	Yes	Same as Reference Predicate Device
PC interface	Yes	Yes	Same
Thermal feedback mechanism	Direct, Thermocouple	Indirect, MR Thermometry	Same as Predicate Device
Usage of software	Yes	Yes	Same
Collection of thermal data	Yes	Yes	Same

510(k) SUMMARY

PERFORMANCE DATA [807.92(b)]

All necessary performance testing was conducted on the Avenda Health Treatment System to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Non-clinical Testing Summary:

The non-clinical, bench testing included:

- Sterilization Validation in accordance with ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*.
- Packaging and shelf life testing in accordance with ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*.
- Biocompatibility evaluation in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process* and FDA Guidance Document titled, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" issued June 16, 2016.
- Software documentation in accordance to FDA's guidance document titled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.
- Software verification and validation testing in accordance to FDA's guidance document titled, "General Principles of Software Validation," issued January 11, 2002.
- Electrical safety and electromagnetic compatibility testing in accordance with the requirements of IEC 60601-1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* and IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*, respectively.
- Non-clinical design verification and validation testing.

The collective results of the non-clinical testing demonstrate that the Avenda Health Treatment System meets the established specifications necessary for consistent performance during its intended use. The collective bench testing furthermore confirm that the Avenda Health Treatment System does not raise different questions of safety or effectiveness for achieving the same intended use of providing laser-based coagulation of soft tissue when compared to the predicate devices.

[807.92(b)(2)] Clinical Testing Summary:

No clinical testing was conducted to support this 510(k) Premarket Notification.

510(k) SUMMARY

CONCLUSIONS [807.92(b)(3)]

The Avenda Health Treatment System (proposed device), the predicate device, Tranberg CLS Thermal Therapy System (K142216), and the reference predicate device, Visualase Thermal Therapy System (K181859) are all designed to coagulate soft tissue using a laser under image guidance with the aid of thermal feedback. The devices have the same Intended Use and similar Indications for Use. The devices also have similar technological characteristics, and any differences in technological differences do not raise different questions of safety and effectiveness. The results of non-clinical performance testing demonstrated that the device meets the established specifications necessary for consistent performance to achieve its intended use as safely and as effectively as the predicate device and reference predicate device and confirmed that the technological differences between the proposed device, predicate device and reference predicate device do not raise different questions of safety or effectiveness. As such, the Avenda Health Treatment System is as safe, as effective, and performs as well as the legally marketed predicate device, Tranberg CLS Thermal Therapy System (K142216), and reference predicate device, Visualase Thermal Therapy System (K181859).