March 26, 2021

Clinical Laserthermia Systems, AB
% David Makanani
CEO
OMEDtech, LLC
1725 Signal Ridge Drive, Suite 150
Edmond, Oklahoma 73013

Re: K201466
Trade/Device Name: Tranberg CLS Laser Applicator
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: February 22, 2021
Received: February 26, 2021

Dear David Makanani:

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,

For 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

Indication for Use

510(k) Number: K201466

Device Name: TRANBERG^{CLS}| Laser Applicator

Indications for Use:

The TRANBERG^{CLS}| Laser Applicator is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy 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, pulmonology, radiology, and urology, for wavelengths 980nm through 1064nm.

Prescription Use: _X___ AND/OR Over-The-Counter Use: NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

510(k)

510(K) SUMMARY

Date	May 23, 2020
SUBMITTER	Lars-Erik Eriksson, CEO Clinical Laserthermia Systems, AB Scheelevagen 2 Lund, Sweden 22381
CONTACT PERSON	Lars-Erik Eriksson, CEO Clinical Laserthermia Systems, AB Scheelevagen 2 Lund, Sweden 22381 Tel: +4646152100 Email: lee@clinicallaser.se
DEVICE NAME	
Classification	Class II
Trade Name	TRANBERG® Laser Applicator
Common Name	TRANBERG® Laser Applicator
Classification	21 CFR 878.4810
Product Code	GEX - Powered Laser Surgical Instrument
Review Panel	General and Plastic Surgery
PREDICATE DEVICE:	K163103, Clinical LaserThermia Systems Tranberg® Laser Diffuser Fiber
INTENDED USE:	The TRANBERG® Laser Applicator is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy 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, pulmonology, radiology, and urology, for wavelengths 980nm through 1064nm.

DEVICE DESCRIPTION:
The TRANBERG® Laser Applicator is used to transfer laser energy from the laser unit to the location for the treatment.

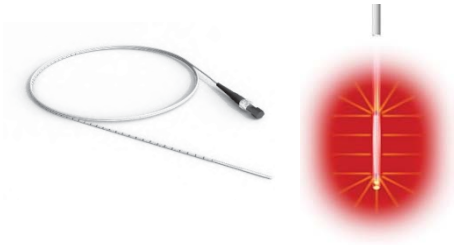
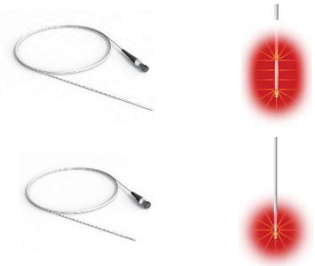
The laser Applicator is designed with a core of 550 µm. The fiber length is 3 and 12m and it has a standard connector SMA 905 to fit the laser unit. The numerical aperture is at 0.22.

The Laser Applicator is used with an introducer and both (fiber and introducer), are delivered sterile and for single use only. The introducer consists of an introducer stylet and introducer catheter with a fiber lock

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

This device is identical in construction and design as the predicate device.

The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Parameter	Predicate	Device
Laser Fiber		
Product name	Tranberg® Laser Diffuser Fiber	Tranberg® Laser Applicator
Manufacturer	Clinical LaserThermia Systems CLS, Sweden	Clinical LaserThermia Systems CLS, Sweden
Indications for use	The Tranberg ® Laser fiber is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy 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, pulmonology, radiology, and urology, for wavelengths 980nm through 1064nm	The Tranberg ® Laser Applicator is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy 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, pulmonology, radiology, and urology, for wavelengths 980nm through 1064nm
Device Regulatory Classification	Accessory to powered surgical laser instrument FDA 878.4810	Accessory to powered surgical laser instrument FDA 878.4810
Product Code	GEX	GEX

Parameter	Predicate	Device
Device Class	Accessory to powered surgical laser instrument Class 2	Accessory to powered surgical laser instrument Class 2
510(k) number	K163013	To be obtained
Fiber core diameter:	550 µm	550 µm
Numerical aperture:	0.22	0.22
Fiber length:	3m, 12m standard	3m, 12m standard
Proximal connector:	SMA 905	SMA 905
Wavelength:	980nm- 1064 nm	980nm-1064 nm
Laser operation mode:	Continuous Wave	Continuous Wave
Diffusing region length:	10- 15 mm	1- 25 mm
Diffusing tip assembly diameter:	1.55 mm	1.55 mm
Lesion Shape:	Elliptical shape	Elliptical or Round shape

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

The Tranberg® Laser Applicator has been determined through engineering testing to support substantial equivalence with this device and the predicate. This testing showed the Tranberg® Laser Applicator to meet applicable ISO, IEC and FDA safety and performance standards.

PERFORMANCE TESTING – CLINICAL

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the TRANBERG® Laser Applicator performs according to specifications, and as intended, and the comparative discussion of intended use, principle of operation, and technological characteristics, has determined that the Tranberg® Laser Applicator is substantially equivalent to the predicate device.