DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 23, 2017

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

Re: K163103
Trade/Device Name: Tranberg CLS Diffusor Laser Fiber
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 6, 2017
Received: February 21, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163103

Device Name
The TRANBERG CLS/Diffusor Laser Fiber

Indications for Use *(Describe)*
The TRANBERG CLS/Diffusor 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.

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

Date	March 22, 2017
SUBMITTER	Lars-Erik Eriksson, CEO
	Clinical Laserthermia Systems, AB
	Scheelevagen 2
	Lund, Sweden 22381
CONTACT PERSON	Lars-Erik Eriksson, CEO
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	Lund, Sweden 22381
	Tel: +4646152100
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DEVICE NAME	
Classification	Class II
Trade Name	TRANBERG[CLS]| Diffusor Laser fiber
Common Name	TRANBERG[CLS]| Diffusor Laser fiber
Classification	21 CFR 878.4810
Product Code	GEX - Powered Laser Surgical Instrument
Review Panel	General and Plastic Surgery
PREDICATE DEVICE:	K151569, Clinical LaserThermia Systems Tranberg [CLS] Laser Fiber
INTENDED USE:	The TRANBERG[CLS]| Diffusor 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.

DEVICE DESCRIPTION:
The TRANBERG[CLS]\| Diffusor Laser fiber is used to transfer laser energy from the laser unit to the location for the treatment.

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

The TRANBERG[CLS]|Diffusor Laser fiber is delivered sterile and for single use only.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

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

Parameter		
Laser Fiber		
Product name	Tranberg [CLS] Laser fiber	Tranberg [CLS] Diffusor Laser Fiber
Manufacturer	Clinical LaserThermia Systems CLS, Sweden	Clinical LaserThermia Systems CLS, Sweden
Indications for use	The Tranberg [CLS] 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 800nm through 1064nm.	The Tranberg [CLS] 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.
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		
Device Class	Accessory to powered surgical laser instrument Class 2	Accessory to powered surgical laser instrument Class 2
510(k) number	K151569	To be obtained
Fiber core diameter:	550 µm	550 µm
Numerical aperture:	0.22	0.22
Fiber length:	3 m	3 - 12m
Proximal connector:	SMA 905	SMA 905
Wavelength:	1064 nm	1064 nm
Laser operation mode:	Continuous Wave	Continuous Wave
Diffusing region length:	1 mm	15 mm
Diffusing tip assembly diameter:	1.55 mm	1.55 mm
Lesion Shape:	Ring shape	Cylindrical shape
Max power:	8 W for 550 µm	20 W for 550 µm
Lesion volume	0.8 cm^3 at 1min/8W; 2.7 cm^3 at 2min/8W	4.6 cm^3 at 2min/15W

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

The Tranberg ^{CLS} Diffusor Laser fiber has been determined through engineering bench testing to support substantial equivalence with this device and the predicates. This testing showed the Tranberg ^{CLS} Diffusor Laser fiber to meet applicable ISO, IEC and FDA safety and performance standards.

Non-clinical bench testing showed the device performed to specification and included:

- Engineering comparative temperature testing

  Performance testing of the fiber was performed in an ex vivo model using bovine cardiac tissue kept at 37 ^{0}C. At a wavelength of 1064 nm using different power settings and exposure times the following parameters where studied:
  - Lesions size
  - Occurrence of carbonization
  - Integrity of the laser fiber

- Biocompatibility Testing
  - ISO 10993-1, Biological Evaluation of Medical Devices
  - ISO 10993-5, Tests for in vitro cytotoxicity
  - ISO 10993-10, Tests for irritation and skin sensitization

- Sterilization/Shelf Life Testing
  - ISO 11135-1, Sterilization of Health-Care Products: Ethylene Oxide

- ISO 10993-7, Biological Evaluation of Medical Devices: Ethylene Oxide
- ISO 11607-1, Packaging for Terminally Sterilized Medical Devices: Requirements
- ISO 11607-2, Packaging for Terminally Sterilized Medical Devices: Validation

PERFORMANCE TESTING – CLINICAL

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the TRANBERG^{CLS}| Diffusor Laser Fiber 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 ^{CLS} Diffusor Laser fiber is substantially equivalent to the predicate device.