April 21, 2015

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

Re: K142216
Trade/Device Name: Tranbergcls Thermal Therapy 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: March 20, 2015
Received: March 24, 2015

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 yours,

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
Indication for Use

510(k) Number: K142216

Device Name: Tranberg CLS Thermal Therapy System

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.”

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 April 17, 2015

SUBMITTER: Lars-Erik Eriksson, CEO
Clinical Laserthermia Systems, AB
Scheelevägen 2
Lund, Sweden 22381

CONTACT PERSON: David Makanani, CEO
OMEDtech, L.L.C.
1725 Signal Ridge Drive, Suite 150
Edmond, Oklahoma 73013
Tel: (405) 826-0713
Email: dmakanani@omedtech.com

DEVICE NAME:

Classification Class II  
Trade Name TRANBERG^{CLS} Thermal Therapy System  
Common Name TRANBERG^{CLS} Thermal Therapy System  
Classification 21 CFR 878.4810  
Product Code GEX - Powered Laser Surgical Instrument  
Review Panel General and Plastic Surgery


INTENDED 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.

DEVICE DESCRIPTION:

The TRANBERG^{CLS} Thermal Therapy System consists of three parts:

- TRANBERG^{CLS} Mobile Laser
• TRANBERG^{CLS}|Temperature Sensor
• Applicator Kit (The Applicator kit is not included)

The mobile laser unit is provided with a laser generator operating at the wavelength 1064 nm. The generated laser light is locally applied by means of a single use applicator kit through a less invasive surgical or percutaneous procedure. The energy within the laser light is absorbed by the tissue resulting in increased tissue temperature. Tissue heating and lesion formation is controlled by a tissue temperature feedback system integrated into the TRANBERG^{CLS}|Thermal Therapy System.

For a detailed description of the function and the usage of the laser module and its accessories, view the IFU.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:
Substantial equivalence of the TRANBERG^{CLS}|Thermal Therapy System is claimed to the PhoTex 30 Diode Laser Series, cleared under K092197.
The CLS device is verified and validated to have the same performance as the predicate device when used together with the Applicator kit cleared under K053087.
The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TRANBERG^{CLS}</th>
<th>Thermal Therapy System</th>
<th>PhoTex 30 Diode Laser Series</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product name</td>
<td>TRANBERG^{CLS}</td>
<td>Thermal Therapy System</td>
<td>PhoTex 30 Diode Laser Series</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Clinical LaserThermia Systems CLS, Sweden</td>
<td>BiTex, US</td>
<td></td>
</tr>
</tbody>
</table>
### 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 PhoTex3 Diode Laser Series 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.”

### Device Regulatory Classification

<table>
<thead>
<tr>
<th>Device Regulatory Classification</th>
<th>FDA</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEX</td>
<td>878.4810</td>
<td>878.4810</td>
</tr>
<tr>
<td>GEX</td>
<td>878.4810</td>
<td>878.4810</td>
</tr>
<tr>
<td>D092197</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Diode laser generator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wavelength</td>
<td>1064nm</td>
<td>980nm, 810nm or 940nm</td>
</tr>
<tr>
<td>Adapted to indication for use of the laser applicator / hand piece</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output power</td>
<td>1W - 25W at output port</td>
<td>3W – 30W at output port</td>
</tr>
<tr>
<td>Output power accuracy</td>
<td>+/- 10% of selected value</td>
<td>+/- 20% of selected value</td>
</tr>
<tr>
<td>Mode of operation</td>
<td>Continuous wave or controlled by tissue temperature monitored by a temperature sensor</td>
<td>Continuous wave (CW), pulsed, or external modulation modes.</td>
</tr>
<tr>
<td>Output power increments</td>
<td>1W</td>
<td>0.5 W</td>
</tr>
<tr>
<td>Cooling</td>
<td>TEC</td>
<td>TEC</td>
</tr>
<tr>
<td>Channel(s)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Output port</td>
<td>SMA 905</td>
<td>SMA 905</td>
</tr>
<tr>
<td>Aiming wavelength</td>
<td>635 nm</td>
<td>650 nm</td>
</tr>
<tr>
<td>Laser type IEC60825-1</td>
<td>Class IV</td>
<td>Class IV</td>
</tr>
</tbody>
</table>

### General technical characteristics

<table>
<thead>
<tr>
<th>General technical characteristics</th>
<th>Power source</th>
<th>Operating temperature range</th>
<th>Average dimensions</th>
<th>Weight</th>
<th>Foot switch operation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100-240 V AC / 50-60 Hz</td>
<td>15ºC to 28ºC</td>
<td>16.0&quot;x12.5&quot;x8.0&quot; (406x318x203)</td>
<td>18 Kg</td>
<td>On/Off</td>
</tr>
<tr>
<td></td>
<td>100-240 V AC / 50-60 Hz</td>
<td>10-35 ºC</td>
<td>20 lbs (9.1kg)</td>
<td></td>
<td>On/Off</td>
</tr>
</tbody>
</table>

Clinical Laserthermia Systems, AB • 223 81 Lund, Sweden

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<table>
<thead>
<tr>
<th>Emergency switch</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key activation of laser output</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Remote Interlock</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Power ON/OFF Visual Indicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Laser Emission Indicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Internal Laser Power Monitor</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Manual Reset</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fiber Insertion Interlock</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Laser Emission Energy Monitoring</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Audio Warning Signal Level</td>
<td>Fixed at HIGH</td>
<td>HIGH, MEDIUM, LOW, and OFF</td>
</tr>
<tr>
<td>Safety classification FDA</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Pump for cooling liquid for applicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Temperature sensors included</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Applicator kit</strong> (Laser fiber and Trochar)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interface</td>
<td>Compatible with fiber optic delivery accessory with a standard SMA905 connector having a core fiber diameter of 400 or 600 microns and a numerical aperture of at least 0.37.</td>
<td>Compatible with fiber optic delivery accessory with a standard SMA905 connector having a core fiber diameter of 400 or 600 microns and a numerical aperture of at least 0.37.</td>
</tr>
<tr>
<td>Performance</td>
<td>The CLS device is verified and validated to have the same performance when used together with the Applicator kit cleared under K053087</td>
<td>The BioTex device is verified and validated together with the Applicator kit cleared under K053087</td>
</tr>
</tbody>
</table>

**PERFORMANCE TESTING - (NON-CLINICAL) BENCH:**

The TRANBERG\textsuperscript{CLS} Thermal Therapy System has been determined through engineering bench testing to support substantial equivalence with this device and the predicates. This testing showed the TRANBERG\textsuperscript{CLS} Thermal Therapy System to meet applicable ISO, IEC and FDA safety and performance standards.

Non-clinical bench performance testing completed:
- Engineering comparative temperature testing
- Engineering Verification and Validation Testing to the Product Requirement Specification
PERFORMANCE TESTING – CLINICAL:

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the TRANBERG<sup>CLS</sup>|Thermal Therapy System performs safely, as intended, and the comparative discussion of intended use, principle of operation, and technological characteristics, it is determined that the TRANBERG<sup>CLS</sup>|Thermal Therapy System is substantially equivalent to predicate devices.
February 12, 2016

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

Re: K151569
   Trade/Device Name: Tranberg CLS 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: January 4, 2016
   Received: January 7, 2016

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.

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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” (21CFR 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.

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Sincerely yours,

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
Indications for Use

TRANBERG CLS Laser fiber

Indications for Use (Describe)
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 at a wavelength of 1064nm.

Type of Use (Select one or both, as applicable)

* Prescription Use (Part 21 CFR 801 Subpart D)  

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*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.*
510(K) SUMMARY

Date
June 1, 2015

SUBMITTER
Lars-Erik Eriksson, CEO
Clinical Laserthermia Systems, AB
Scheelevägen 2
Lund, Sweden 22381

CONTACT PERSON
Lars-Erik Eriksson, CEO
Clinical Laserthermia Systems, AB
Scheelevägen 2
Lund, Sweden 22381
Tel: +4646152100
Email: lee@clinicallaser.se

DEVICE NAME
Classification
Class II
Trade Name
TRANBERG\textsuperscript{CLS} Laser fiber
Common Name
TRANBERG\textsuperscript{CLS} Laser fiber
Classification
21 CFR 878.4810
Product Code
GEX - Powered Laser Surgical Instrument
Review Panel
General and Plastic Surgery

PREDICATE DEVICE:
K053087, Visualase Cooled Laser Application System (VCLAS)

INTENDED USE:
The TRANBERG\textsuperscript{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, at a wavelength of 1064nm.

DEVICE DESCRIPTION:
The TRANBERG\textsuperscript{CLS} Laser fiber is used to transfer laser energy from the laser unit to the location for the treatment.
The laser fiber is an optical fiber with a core of 550 mic and radial diffusor. The length is 3m and it has a standard connector SMA 905 to fit the laser unit. The numerical aperture is at 0.22. The material in contact with human tissue is biocompatible.

The TRANBERG<sup>CLS</sup> 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:

<table>
<thead>
<tr>
<th>Product name</th>
<th>Tranberg &lt;sup&gt;CLS&lt;/sup&gt; Laser fiber</th>
<th>Visualase Laser fiber LDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Clinical LaserThermia Systems CLS, Sweden</td>
<td>BioTex Inc., US</td>
</tr>
<tr>
<td>Intended use / Indications for use.</td>
<td>The Tranberg &lt;sup&gt;CLS&lt;/sup&gt; 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, at a wavelength of 1064nm.</td>
<td>The LDF 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.</td>
</tr>
<tr>
<td>Device Regulatory Classification</td>
<td>Accessory to powered surgical laser instrument</td>
<td>Accessory to powered surgical laser instrument</td>
</tr>
</tbody>
</table>
Clinical Laserthermia Systems, AB • 223 81 Lund, Sweden

GDOC-2015-042

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

The Tranberg CLS 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 Laser fiber to meet applicable ISO, IEC and FDA safety and performance standards,

Non-clinical bench performance testing completed:
- Engineering comparative temperature testing
- Biocompatibility

PERFORMANCE TESTING – ANIMAL/CLINICAL

There are no animal or clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the TRANBERG CLS 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 Laser fiber is substantially equivalent to the predicate device.