K071328

510(k) Summary

In accordance with the Safe Medical Devices Act of 1990 and in compliance with 21CFR 807, the following serves as the 510(k) Summary information upon which the substantial equivalence determination is based.

Contact Information

Submitter: BioTex, Inc.
8058 El Rio St.
Houston, TX 77054

Phone: 713-741-0111

Contact Person: Matthew Fox

AUG 3 1 2007

Date Prepared: 5/11/2007

Device Names

Trade Name/s: Visualase® Thermal Therapy System.

Common Name: Magnetic Resonance Image Guided Laser Thermal Therapy System

Classification: Picture Archiving and Communications System,
Powered Surgical Laser Instrument/Applicator,
Infusion Pump

Product Code: LLZ (Image Processing System),
GEX (Surgical Laser, Laser Applicator),
FRN (Infusion Pump)

Reg.Class: Class II

Reg. Number: 21CFR892.2050 (LLZ)
21CFR878.4810 (GEX)
21CFR880.5725 (FRN)

Predicate Devices

Visualase ENVISION MRI Analysis Software by BioTex, Inc. K063505
PhoTex15 Surgical Diode Laser System by BioTex, Inc. K060304
Visualase Cooled Laser Applicator System by BioTex, Inc. K053087
K-pump by Kolster Methods, Inc. K991203

Description of Device

The Visualase Thermal Therapy System comprises four devices: a laser energy source, a cooled laser applicator, a pump for circulating coolant through the applicator, and a computer workstation with magnetic resonance imaging (MRI) analysis software for determination and visualization of relative changes in tissue temperature during therapy.

The four components have themselves been previously cleared for marketing via 510(k) notifications with the new device bringing these four components into a single portable cart for use in MR-guided laser thermal therapy procedures. In practice, all of the devices are used according to their approved indications for use. That is, the laser applicator is introduced into the tissue to be destroyed and connected to both the laser energy source and the cooling pump. The

cooling pump and laser are operated as normal to deliver energy and cause tissue ablation. Since the laser applicator is MR-compatible, the laser ablation procedure may be carried out inside of an MRI magnet. In this case, appropriate MR imaging can be performed during the treatment, and the MR analysis software can be used to evaluate the thermal changes in the target tissue. For example, the Visualase system can process real and imaginary image data from gradient recalled echo sequences 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. Thus, the laser thermal therapy procedure can be performed under MR image guidance.

It is important to note that the functions and uses of the constituent components of the Visualase Thermal Therapy System remain unchanged from their currently approved labeling and indications statements. In particular, the operation of the ENVISION analysis software provides passive monitoring of the laser treatment, and the operation of the laser, applicator, and pump are independent of the MR imaging. The combination of these devices into a single system, however, provides a convenience to the user who will perform laser thermal therapy treatments under MR image guidance. Thus, the indications for use statement for the combined system now describes that the system may be used for laser thermal therapy treatments under magnetic resonance imaging guidance.

Indications for Use

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 sequences is available, the Visualase system can process images to determine 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.

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.

Comparison to Predicate Devices

The Visualase Thermal Therapy System indications for use are the same as those of the individual components except that, when used together as a system, the laser thermal treatment may be performed under MRI guidance.

Non-clinical Performance Tests

Performance and technical data for each of the components of the Visualase Thermal Therapy System are unchanged from those listed in the original submissions and are therefore not included here.

Conclusion

The Visualase Thermal Therapy System is substantially equivalent to predicate devices. The combination of the devices into a system does not affect the specifications, functions, or performance of any of the individual devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2007

Bio Tex, Inc.
8058 El Rio Street
% Mr. Matthew Fox
Engineering Manager
Houston, TX 77054

Re: K071328
Trade/Device Name: Visualase® 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: II
Product Code: GEX
Dated: August 28, 2007
Received: August 29, 2007

Dear Mr. Fox:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

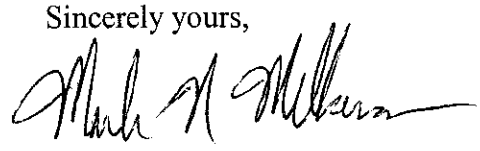
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071328

Device Name: Visualase Thermal Therapy System

Indication For Use:

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 sequences is available, the Visualase system can process images to determine 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.

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.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071328