K 081656

SEP 10 2008

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.
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Date Prepared: 7 May 2008

Device Names

Trade/Proprietary Name: Visualase® Thermal Therapy System

Common Name: Magnetic Resonance Image-Guided Thermal Therapy System

Classification Name: Picture Archiving and Communication 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 Thermal Therapy System, K071328.

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. A software application running on the workstation allows the workstation user to control the laser output and to operate the coolant pump from the workstation interface. Additionally, when appropriate thermal imaging guidance is used, temperature limits may be associated with prescribed image locations and used as an interlock for automatic deactivation of the laser output.

A previous version of the Visualase Thermal Therapy System has been cleared for marketing via 510(k) notification (Visualase Thermal Therapy System, K071328). The instant version of this system extends the functionality of the predicate version by providing a software interface for control of the laser output through the computer interface port of the laser component and on/off operation of the pump through a similar interface. When used with appropriate magnetic resonance thermal imaging guidance, a software tool may be used to prescribe limits for the temperature at certain points in the image which can, in turn, be used to deactivate the laser if the limits are reached. Thus this system provides an additional level of "interlock" security over the previous version which may increase safety and/or precision of the treatment prescription. It is important to note that while temperature image information can be used to automatically deactivate the laser as a safety precaution, the user may, at his discretion, override the interlock and proceed with additional laser energy deposition if warranted. Further, it is important to note that the added security feature is in no way capable of energizing the laser on its own. The laser may ONLY be activated by a deliberate action from the user. Thus the added feature serves only as an additional safety interlock on the laser system similar to many other common safety features.

Computer control of the coolant pump status (ON/OFF) provides an additional convenience to the user and also provides an additional safety feature since, when the laser is operated from the workstation interface, activation of the laser can be made dependent on first activating the coolant pump.

The addition of these features to the Visualase system has no effect on the Indications for Use statement which remains unchanged from the predicate device (except that we have now extended compatibility to Siemens MRI systems).

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 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.

Comparison to Predicate Devices

The indications for use for the newest Visualase Thermal Therapy System are essentially the same as those of the antecedent system except that compatibility has been extended to Siemens Medical Solutions MRI systems.

Non-clinical Performance Tests

Performance, specifications, and technical data for the components of the Visualase component devices are essentially unchanged from the previous version, and are therefore not included here.

Conclusion

The instant version of the Visualase Thermal Therapy System is substantially equivalent to the predicate version. The additional features do not affect the specifications or function of the system as a whole.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2008

BioTex, Inc.
% Roger McNichols, Ph.D.
Vice President
8058 El Rio Street
Houston, Texas 77054

Re: K081656
Trade/Device Name: Visualase Thermal Therapy System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, GEX, FRN
Dated: June 9, 2008
Received: June 12, 2008

Dear Dr. McNichols:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Indications for Use Statement

510(k) Number (if known): K 081656

Device Name:

Indications for Use:

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

510(k) Number K081656