MAR 1 2006

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:	Ashok Gowda, PhD
Date Prepared:	11/01/2005

Device Names

Trade Name:	Laser Diffusing Fiber (LDF) Cooling Catheter System (CCS) Bare Tip Fiber (BTF)
Proprietary Name:	Visualase Cooled Laser Application System (VCLAS)
Common Name:	Diffusing laser fiber or probe Cooling catheter or sheath Bare tip laser fiber or probe
Classification:	Accessory to powered surgical laser instrument

Predicate Device

SLT Diffuser™ Fiber (K010041)
Indigo Bare-Tip™ Fiberoptic (K963081)

Description of Device

The VCLAS family consists of three components, the LDF, CCS, and BTF. The LDF and BTF transmit laser energy to the tissue situated at their distal regions. The LDF is comprised of a standard silica fiber optic cable affixed with a diffusing tip assembly. The diffusing tip assembly is comprised of a plastic tube that is filled with a transparent matrix in which light dispersing particles are embedded. The distal end of the tube is sealed with a higher concentration of scattering

particles in a conical structure to prevent significant forward transmission of energy.

The LDF may be used with a cooling catheter, in particular the compatible CCS, but such a catheter is not required. The CCS can be employed with or without coolant flow. The use of coolant provides cooling for the surfaces of the CCS in contact with both the tissue and the LDF.

The BTF is comprised of a standard silica fiber optic cable identical to fiber optic used in the LDF. The distal end of the BTF is terminated in a flat, polished face and is designed for use in both contact and non-contact applications.

Indications for Use

The LDF and CCS are 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 Bare Tip Fiber (BTF) is intended for use in vaporization, cutting, ablation and coagulation of soft tissues with or without scopes or handpieces, for contact or non-contact surgery in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels of the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology and urology for the wavelength range of 800nm through 1064nm.

Comparison to Predicate Device

The Laser Diffusing Fiber (LDF) and Cooling Catheter System (CCS) have been shown to be substantially equivalent to the SLT Diffuser™ fiber (K010041). The Bare Tip Fiber (BTF) has been shown to be substantially equivalent to the bare tip fiber marketed with the Indigo Diffuser Fiberoptic (K963081). Differences were determined to be minor and are each within the specifications listed by the predicate devices and does not raise any concerns regarding the overall safety and effectiveness of the device.

Non-clinical Performance Tests:

Engineering studies have demonstrated the substantial equivalence of the Laser Diffusing Fiber (LDF) to the SLT Diffuser Fiber Delivery Systems (K 010041).

The studies concluded that the treated tissue displayed an ellipsoidal coagulation area surrounding the diffusing region of the laser diffusing fiber. In all instances,

the fiber and lasers functioned as intended and performed in a manner similar to the predicate device when used in accordance with the labeled directions for use and specified indications.

The materials used in the Visualase Laser Diffusing Fiber (LDF), Cooling Catheter System (CCS), and Bare Tip Fiber (BTF) were determined to be biocompatible according to appropriate international test standards.

Conclusion

BioTex has demonstrated the Visualase Laser Diffusing Fiber (LDF), Cooling Catheter System (CCS), and Bare Tip Fiber (BTF) are substantially equivalent to the predicate devices based on design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2006

BioTex, Inc.
c/o Ashok Gowda, Ph.D.
President
8058 El Rio Street
Houston, Texas 77054

Re: K053087
Trade/Device Name: Visualase Cooled Laser Application 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: January 5, 2006
Received: January 20, 2006

Dear Dr. Gowda:

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.

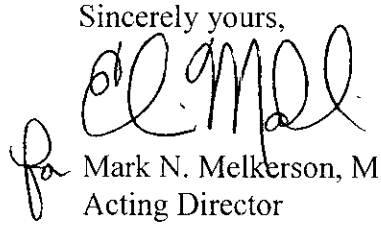
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson, M.S.
Acting 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): K053087

Device Name: Visualase Cooled Laser Application System (VCLAS)
Laser Diffusing Fiber (LDF)
Cooling Catheter System (CCS)
Bare Tip Fiber (BTF)

Indications for Use:

The Visualase Cooled Laser Applicator System (VCLAS) is comprised of a Laser Diffusing Fiber (LDF), a Cooling Catheter System (CCS), and a Bare Tip Fiber (BTF).

The Laser Diffusing Fiber (LDF) and Cooling Catheter System (CCS) are 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 of the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology and urology for the wavelength range of 800nm through 1064nm.

The Bare Tip Fiber (BTF) is intended for use in vaporization, cutting, ablation and coagulation of soft tissues with or without scopes or handpieces, for contact or non-contact surgery in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels of the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology and urology for the wavelength range of 800nm through 1064nm.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053087