510(k) SUMMARY K062363

The Summary of Safety and Effectiveness on the B&W Tek, Inc. BWF-5 Medical Laser Series reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Sean Wang, Ph.D. B&W Tek, Inc. 19 Shea Way, Suite 301 Newark, Delaware 19713 JAN 17 2007
Telephone	302-368-7824
Facsimile	302-368-7830
Date	July 31, 2006
Name	BWF-5 Medical Laser Series
Classification	Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810
Predicate:	• K060304 BioTex, Inc., PhoTex 15 Diode Laser Series: 810, 940, 980, market clearance date March 21, 2006; and • K972575 Laserscope, 800 Series Surgical Laser System Orion Surgical Laser System Angled Delivery Devices (ADD Family Product Line), market clearance date July 17, 1998.
Description	BWF-5 Solid-State Medical Laser Series are highly reliable, compact and easy to operate medical laser systems. The cutting edge control technology provides user a high reliable and maintenance free system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight hand piece. Activation occurs when the operator enables the laser and presses the foot switch. Release the foot switch to deactivate the laser. Depending on laser system configuration, the foot switch can function as on/off switch. A convenient and easy-to-use touch-screen display panel allows the operator to adjust or set laser output level with minimal effort. The laser can operate in continuous wave mode or controlled pulse mode. The device features multiple user-programmable presets for storing frequently used treatment parameters.
Intended Use	The BWF-5 Medical Laser Series are intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The BWF-5 Medical Laser Series are generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery and thoracic surgery.

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Warning	• NEVER look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated WITH or WITHOUT the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes and skin. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. • DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure. • DO NOT attempt to gain access to any internal device component. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury. • AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N_2O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. • FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.
Cautions:	• Never allow untrained personnel to operate this advice unless directly supervised by a properly trained and experienced individual • The protective eyewear supplied with this device has an optical density rating >5 in the 350nm~2000nm (see specification sheet) region. All personnel present during device operation must ware this eyewear. Contact B&W Tek at 302-368-7824 to purchase additional sets of protective eyewear for this device.

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Caution continued	• Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser. • Place "Laser in use" signs at location entrances where people will use the B&W Tek, Inc. laser device. • Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the hand or piece or fiber optic. • Never leave this device in the READY mode unattended. See the STANDBY to READY Mode in the Operations section of this manual. • Remove the key from the device's key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions. • Turn the device off before relocating equipment in the same vicinity. • Never press the foot switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions. • During any laser procedure, do not allow any nonessential personnel into the treatment area. • Never allow the untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual. • ALWAYS clean the SMA fiber tip before inserting into the SMA emission port. A dirty tip could result in damage to the unit.
Substantial Equivalency Information	The BWF – 5 Medical Laser Series has the same intended use and the same technological characteristics as the predicate devices listed. The identified differences were determined to be minor and are each within the specifications listed by the predicate device and does not raise any concerns regarding the overall safety and effectiveness of the device.
Technological Characteristics	The device is subject to the following voluntary consensus standards: 21 C.F.R. § 1040.10 & 1040.11; IEC 60601-1; IEC 60601-1-2; IEC 60601-1-4; IEC 60601-2-22; IEC 61000-3-2; IEC 61000-3-3; and IEC 60825-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

B&W Tek, Inc.
% Sean Wang, Ph.D.
Managing Director
19 Shea Way, Suite 301
Newark, Delaware 19713

JAN 17 2007

Re: K062363
Trade/Device Name: BWF-5 Medical Laser Series
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: December 12, 2006
Received: December 14, 2006

Dear Dr. Wang:

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 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

510(k) Number (if known): K062363

Device Name: BWF-5 Medical Laser Series

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062363

Prescription Use _____ Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)