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510(k) SUMMARY
BFW, Inc.
ChromaLUME Turbo Light Source
With
XtremeBeam Fiber Optic Headlight

K093386

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

BFW, Inc.
2307 River Road, Suite 103
Louisville, Kentucky, 40206

Contact Person:

Lynn Cooper
President/CEO
BFW Inc.

Date Prepared: October 15, 2009

Name of Device and Name/Address of Sponsor

BFW, Inc. ChromaLUME Turbo Light Source With XtremeBeam Fiber Optic Headlight

BFW, Inc.
2307 River Road, Suite 103
Louisville, Kentucky, 40206

Common or Usual Name

Surgical Lamp

Classification Name

Lamp, Surgical Fiberoptic

Predicate Device

Welch Allyn, Inc. Model ProXenon 350 Surgical Illuminator **(K071218).**

Intended Use

The ChromaLUME Turbo Light Source is designed for use with fiber optic headlight systems to supply high intensity light through the fiber optic

cable for illumination of a surgical field. It will accommodate fiber optic cables from Wolf, Storz, Olympus and ACMI/BFW products.

The XtremeBeam Fiber Optic Headlight is a passive luminary which is illuminated by the fiber optic light to provide supplemental light for surgical procedures.

Technological Characteristics and Substantial Equivalence

A. **Device Description**

The ChromaLUME Turbo Light Source is designed for use with fiber optic headlight systems. Its' intended function and use is to supply high intensity light through the fiber optic cable for illumination of a surgical field. The ChromaLUME Turbo Light Source will accommodate fiber optic cables from Wolf, Storz, Olympus and ACMI/BFW products.

The XtremeBeam Fiber Optic Headlight is a passive luminary which is illuminated by the fiber optic light to provide supplemental light for surgical procedures. It is constructed of a durable plastic housing, lenses, spot size adjustment, and positioning bar. It utilizes a proprietary fiber optic cable, the distal end of which will fit an ACMI port. The luminaire optics consist of optic lenses, a mirror, and an iris.

B. Substantial Equivalence

The ChromaLUME Turbo Light Source with XtremeBeam Fiber Optic Headlight is substantially equivalent to the Welch Allyn, Inc. Model ProXenon 350 Surgical Illuminator **(K071218).**

Performance Data

The ChromaLUME with XtremeBeam has been tested to and meets IEC 60601-1 Standard for Medical electrical equipment, Part 1: General requirements for safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 2 8 2010

BFW, Inc.
% Ms. Lynn Cooper
President/CEO
2307 River Road
Suite 103
Louisville, Kentucky 40206

Re: K093386
Trade/Device Name: ChromaLUME Turbo Light Source™ with XtremeBeam™ Fiber Optic Headlamp
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: October 15, 2009
Received: October 30, 2009

Dear Ms. Cooper:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): TBD K093386

Device Name: ChromaLUME Turbo Light Source™ with XtremeBeam™ Fiber Optic Headlamp

Indications for Use:

The ChromaLUME Turbo Light Source is designed for use with fiber optic headlight systems to supply high intensity light through the fiber optic cable for illumination of a surgical field. The ChromaLUME Turbo Light Source will accommodate fiber optic cables from Wolf, Storz, Olympus and ACMI/BFW products.

The XtremeBeam Fiber Optic Headlamp is a passive luminary which is illuminated by the fiber optic light to provide supplemental light for surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (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)

Mark A. Milleson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093386