K080962

510(k) SUMMARY
Thompson Surgical Instruments, Inc. Lite Wand II

JUN 25 2008

Applicant: Stephanic A. Zalucha
Thompson Surgical Instruments Inc.
10170 E. Cherry Bend Road
Traverse City, MI 49684
Tel: 231-922-5170
Fax: 231-922-0174

Registration #: 1450428

Date Summary Prepared: January 16, 2008

Trade Name: Lite Wand II

Classification Name: Surgical Lamp

Common or Usual Name: Light, Surgical, Fiber Optic

Device Description: Thompson Surgical Instruments, Inc. Lite Wand II is a fiber optic surgical light designed to provide visible illumination of the surgical field or the patient. The Lite Wand II consists of a Cam Joint fixture which attaches the device to a retractor system arm, a flexible "gooseneck" supported lighthead for easy positioning, and a fiber optic bundle. The Thompson surgical Lite Wand II is designed as a task light for surgical use.

The Lite Wand II is designed to be a replacement or substitute for headlamps and it uses the same technology currently used in other headlamps and light sources. These other devices have similar performance characteristics which have been previously cleared by the FDA.

Intended use: The Thompson Surgical Instruments, Inc. Lite Wand II intended as a task light for surgical procedures. It is designed to be used in conjunction with a retractor system which it can attach to through the use of a Cam Joint. The Lite Wand II is designed to provide visible illumination of the surgical field or the patient through a Halogen light source only. The Lite Wand II is designed to be used by surgeons and other medical care practitioners in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2008

Thompson Surgical Instruments, Inc.
% Ms. Stephanie A. Zalucha
Product Manager
10170 East Cherry Bend Road
Traverse City, Michigan 49684

Re: K080962
Trade/Device Name: Lite Wand II
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FST
Dated: May 22, 2008
Received: June 12, 2008

Dear Ms. Zalucha:

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

510(k) Number (if known): K080962

Device Name: Lite Wand II

Indications For Use:

The Thompson Surgical Instruments, Inc. Lite Wand II intended as a task light for surgical procedures. It is designed to be used in conjunction with a retractor system which it can attach to through the use of a Cam Joint. The Lite Wand II is designed to provide visible illumination of the surgical field or the patient through a Halogen light source only. It is intended to be used with ACMI, Storz, Wolf, or Olympus connector cables. The Lite Wand II is intended to be used by surgeons and medical care practitioners in a surgical setting.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

510(k) Number K080962

Concurrence of CDRH, Office of Device Evaluation (ODE)