

K083710

**510(k) SUMMARY**  
**Thompson Surgical Instruments, Inc. Retractor Lite** FEB 23 2009

**Applicant:** Stephanie 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:** July, 15 2008

**Trade Name:** Retractor Lite

**Classification Name:** Surgical Lamp

**Common or Usual Name:** Light, Surgical, Fiber Optic

**Device Description:** Thompson Surgical Instruments, Inc. Retractor Lite is a fiber optic surgical light designed to provide visible illumination of the surgical field or the patient. The Retractor Lite consists of a flexible "gooseneck" supported lighthouse for easy positioning, a fiber optic bundle, and two molded clips made of TECASON™ P XRO used to attach the gooseneck portion of the light to a retractor blade. The Thompson surgical Retractor Lite is designed as a task light for surgical use.

The Retractor Lite 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. Retractor Lite intended as a task light for surgical procedures. It is designed to be used in conjunction with a retractor blade which it can attach to through the use of TECASON™ P XRO clips. The Retractor Lite is designed to provide visible illumination of the surgical field or the patient through a Xenon light source only. The Retractor Lite is designed to be used by surgeons and other medical care practitioners in a surgical setting.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 23 2009

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

Re: K083710  
Trade/Device Name: Retractor Lite  
Regulation Number: 21 CFR 878.4580  
Regulation Name: Surgical lamp  
Regulatory Class: II  
Product Code: FST  
Dated: February 12, 2009  
Received: February 17, 2009

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.

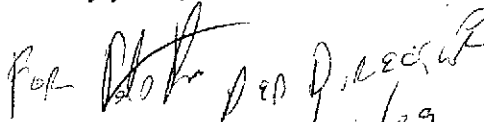
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 2/26/09  
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): K083710

Device Name: Retractor Lite

Indications For Use:

The Thompson Surgical Instruments, Inc. Retractor Lite intended as a task light for surgical procedures. It is designed to be used in conjunction with a retractor blade which it can attach to through the use of TECASONTM P XRO clips. The Retractor Lite is designed to provide visible illumination of the surgical field or the patient through a Xenon light source only. The Retractor Lite is designed to be used by surgeons and other medical care practitioners in a surgical setting.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Pople  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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