zimmer
spine

510(k) SUMMARY
Zimmer® MIS Light

510(k) Number 080367

FEB 22 2008

Date of Summary Preparation:	February 11, 2008
Manufacturer:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439
Company Contact:	Elsa A. Linke Senior Regulatory Affairs Specialist
Device Name:	Zimmer® MIS Light
Common Name:	MIS Light
Classification Name:	Light, Surgical, Fiber optic
Product Code:	FST
Regulation Number:	21 CFR 878.4580
Device Classification:	Class II
Predicate Devices:	NuVasive MaXcess Light Guide, K042034

Description of Device: The *Zimmer* MIS Light consists of fiber optic cables contained within silicone tubing which can be connected on one end to a hospital provided light source and to a *Zimmer* surgical access instrument on the other end. Light is transmitted from the hospital light source through the cable directly to the surgical site. The *Zimmer* MIS Light is provided sterile for single-use only. The Light was tested for compatibility with different types of light sources ranging from 150 Watts to 300 Watts.

Intended Use: The *Zimmer* MIS Light is intended to provide surgical site illumination from a high intensity light source.

Comparison of Technological Characteristics:

The *Zimmer* MIS Light shares the same technological characteristics as the predicate device. These characteristics include similar design, technical requirements, materials, and intended use.

Substantial Equivalence:

The *Zimmer* MIS Light is substantially equivalent to the predicate device in design, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

Zimmer Spine, Inc.
% Ms. Elsa A. Linke
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K080367
Trade/Device Name: Zimmer® MIS Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp.
Regulatory Class: II
Product Code: FST
Dated: February 11, 2008
Received: February 12, 2008

Dear Ms Linke:

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 Statement

510(k) Number (if known): K080367

Device Name: **Zimmer® MIS Light**

Indications for Use: The *Zimmer* MIS Light is intended to provide surgical site illumination from a high intensity light source.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080367