FEB 1 8 2009

510(k) Summary
Axxion™ Light Guide

510(k) Number K082992

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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760-607-0121

Contact Information:
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Date Prepared: October 3, 2008

Device Identification

Proprietary Name	Axxion™ Light Guide
Common Name	Light Guide
Classification Name	Light, Surgical, Fiberoptic
Device Classification	21 CFR 878.4580 (Surgical Lamp)
Proposed Regulatory Class	Class II
Device Product Code	FST

Device Description

The Axxion Light Guide is a bifurcated light guide that stems from a single cable and branches twice to terminate into four cables with illumination tips at each distal end. The end existing as a single cable contains a universal light source adapter that can be attached to a multitude of high intensity external light sources (ranging from 150 Watts to 300 Watts). Light provided from the external source is propagated through fiberoptic bundles contained by a jacket made of silicone sheathe. Fiberoptic bundles terminate at four stainless steel illumination tips that deliver light to the surgical site.

Intended Use of the Device

The Axxion Light Guide is intended to provide surgical site illumination from a high intensity light source.

Substantial Equivalence

The Axxion Light Guide was shown to be substantially equivalent in design, technical requirements, materials, and intended use to the following predicate devices: Medical Light Guide by Fiberoptics Technology, Inc. (K904378), MIS Light by Zimmer (K080367), and MaZcess Light Guide by NuVasive (K042034).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Spinal Elements, Inc.
% Ms. Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K082992
Trade/Device Name: Axxion™ Light Guide
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FST
Dated: February 10, 2009
Received: February 11, 2009

Dear Ms. DiMartino:

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): k082992

Device Name: Axxion™ Light Guide

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

Prescription Use __X___ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082992