510k Summary

K122637

510(k) Summary of Safety and Effectiveness

NOV 1 2012

Stryker Spine - LITe® Decompression System - Light Cable

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Tina Mornak Regulatory Affairs Associate Phone: 201-760-8193 Fax: 201-962-4193 Email: tina.mornak@stryker.com
Date Prepared	October 25, 2012
Trade Name	Stryker Spine - LITe® Decompression System - Light Cable
Proposed Class	Class II
Classification Name and Number	Light, Surgical, Fiber optic 21 CFR 878.4580
Common Name	Surgical lamp
Product Code	FST
Predicate Devices	NuVasive MaXcess Light Guide: K042034 Zimmer MIS Light: K080367
Device Description	The Stryker Spine LITe® Decompression System - Light Cable is a single use, sterile and disposable component. The Stryker Spine LITe® Decompression System - Light Cable consists of fiber optic cables contained within silicone tubing which can be connected to a light generator on one end and the tube of the Stryker Spine LITe® Decompression System on the other end.
Intended Use	The Stryker Spine LITe® Decompression System - Light Cable is intended to provide surgical site illumination from a high intensity light source when Stryker decompression tubes are in use.
Summary of the Technological Characteristics	The LITe® Decompression System – Light Cable shares the same technological characteristics as the predicate devices. These characteristics include similar design, technical requirements, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Stryker Spine
% Ms. Tina Mornak
Regulatory Affairs Associate
2 Pearl Court
Allendale, New Jersey 07401

NOV 1 2012

Re: K122637
Trade/Device Name: Stryker LITe ® Decompression System-Light Cable
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: August 23, 2012
Received: August 29, 2012

Dear Ms. Mornak:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S
2012.11.05 10:44:24 -05'00'

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

Enclosure

Indications for Use

510(k) Number (if known): K 122637

Device Name: Stryker LITe® Decompression System – Light Cable

Indications for Use:

The Stryker Spine LITe® Decompression System - Light Cable is intended to provide surgical site illumination from a high intensity light source when Stryker decompression tubes are in use.

Mark P Ogle for nsm

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

510(k) Number K122637

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)