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ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Abbott Spine, Inc.
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	David Padgett Senior Specialist, Regulatory Affairs Telephone: (512) 533-1998 Fax: (512) 258-0995
DATE:	02 June 2009
TRADE NAME:	NEXLINK OCT® Cervical Plating System
PRODUCT CODE:	KWP
CLASSIFICATION NAME:	OCCIPITAL CERVICAL PLATING SYSTEM
CLASSIFICATION REFERENCE:	21 CFR § 888.3050
PREDICATE DEVICE:	OctaFix® Occipital Cervical Fixation System, K021009, Abbott Spine, cleared 18 June 2002.

DEVICE DESCRIPTION:

NexLink OCT is the re-design and modernization of the existing OctaFix system. The scope of the NexLink OCT Cervical Plating System will include 1) a modular occipital plate, 2) a selection of pre-contoured rods, 3) hooks and 4) a refined set of instrumentation. The scope of the project is for NexLink OCT to integrate as an option to the current Nex-Link System. The NexLink OCT Occipital Cervical Plating System components are temporary implants that are used to stabilize the spine (occiput-T3) during the development of a solid spinal fusion in patients with degenerative disease, trauma (including fractures), and tumor pathology.

INDICATIONS:

The NexLink OCT Occipital Cervical Plating System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlanto-axial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors.

The Cancellous and Cortical Bone Screws (3.5mm and 4mm diameters; 6mm-20mm threaded lengths) are used with the NexLink OCT Occipital Cervical Plating System to allow for occipital fixation and limited to occipital fixation only. The 4mm Cannulated Side Loading Closed Screws are limited to placement in the upper thoracic spine (T1-T3) for additional stabilization of the cervical spine for the indications specified above.

COMPARISON TO PREDICATE DEVICE:	The subject device is the result of modifications to the existing Occipital Cervical Plating System. The subject device has the same intended use and is substantially equivalent to the aforementioned predicate device.
PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):	Non-Clinical Performance and Conclusions: Laboratory and bench testing results demonstrate that the proposed device is substantially equivalent to the predicate device. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Abbott Spine, Inc.
c/o Mr. David Padgett
Senior Specialist, Regulatory Affairs
5301 Riata Park Ct., Bldg F
Austin, Texas 78727

JUN - 2 2009

Re: K090060
Trade/Device Name: NexLink OCT Cervical Plating System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: May 26, 2009
Received: May 27, 2009

Dear Mr. Padgett:

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 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/cdrh/comp/ 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090060

Device Name: NEX-LINK OCT® Cervical Plating System

Indications for Use:

The Nex-Link OCT Occipital Cervical Plating System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlanto-axial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors.

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

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

510(k) Number K090060