510(k) Summary
Life Spine Anterior Lumbar Fixation System (Presidio™)

Submitted By: Life Spine, Inc.
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JAN 19 2010

510(k) Contact: Charles P. Gill
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Date Prepared: October 6, 2009

Trade Name: Life Spine Anterior Lumbar Fixation System (Presidio)

Common Name: Spinal Fixation System

Classification: KWQ, 21 CFR 888.3060, Class II

Device Description:
The Life Spine Anterior Lumbar Fixation System (Presidio) consists of a variety of plates and screws. Implant components can be rigidly locked to suit the individual pathology and anatomical conditions of the patient.

Intended Use of the Device:
The Life Spine Anterior Lumbar Fixation System (Presidio) is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

Performance Data:
Biomechanical testing in accordance with appropriate ASTM standards was conducted to demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence:
The Life Spine Anterior Lumbar Fixation System (Presidio) was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 19 2010

Life Spine
% Mr. Charles P. Gill
Director Regulatory Affairs/
Quality Assurance Manager
2401 W. Hassell Road - Suite 1535
Hoffman Estates, Illinois 60169

Re: K093200
Trade/Device Name: Life Spine Anterior Lumbar Fixation System (Presidio™)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 04, 2010
Received: January 05, 2010

Dear Mr. Gill:

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/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,

Barbara Buehrer for

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): _____

Device Name: **Life Spine Anterior Lumbar Fixation System (Presidio™)**

Indications for Use: The **Life Spine Anterior Lumbar Fixation System (Presidio)** is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

Prescription Use √ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K093200

8. 510(k) Summary

Sponsor: Nexxt Medical, Inc.
10142 Brooks School Road
Fishers, IN 46037
Phone (317) 436.7801
Fax (317) 245.2518

JAN 19 2010

Contact Person: Andy Elsbury, President

Proposed Trade Name: Blade™ Anterior Cervical Plate System

Device Classification Class II

Classification Name: Appliance, fixation, spinal intervertebral body

Regulation: 888.3060

Device Product Code: KWQ

Device Description: The Blade™ Anterior Cervical Plate System consists of and screws and plates in a variety of sizes. One-, two- and three-level plates are offered. Screws are available in two diameters in both self-tapping and self-drilling versions. The Blade™ Anterior Cervical Plate System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or titanium (Grade 2 or 4) as described by ASTM F67.

Intended Use: The Blade™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

WARNING: The Blade™ Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Substantial Equivalence: Documentation was provided which demonstrated the Blade™ Anterior Cervical Plate System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and mechanical performance.