K072116

510(k) Summary according to 807.92(c)

Contact: Randolph Bishop, M.D.
Neurospine Innovations and Solutions
14 Cotesworth Place
Savannah, GA 31411
912-958-4853

MAR 20 2008

Trade Name: Savannah Lumbar Percutaneous Stabilization System

Classification: 21 CFR §888.3070 Pedicle Screw Spinal System
§888.3050 Spinal Interlaminal Fixation Orthosis

Class: III

Product Codes: MNI, MNH, NKB

Indications for Use:

The Savannah Lumbar Percutaneous Stabilization System (SLPSS) is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

When used as a pedicle screw fixation system of the posterior lumbar spine in skeletally mature patients, the SLPSS is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) spinal tumor, and/or (5) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the SLPSS is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

The Savannah Lumbar Percutaneous Stabilization System (SLPSS) is also intended to provide immobilization and stabilization of the spinal segments of the lumbar and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

Device Description:

The Savannah Lumbar Percutaneous Stabilization System is comprised of a variety of pedicle screws sizes, couplers, a ball swivel, rods and locking nuts that can be uniquely fitted for each individual case. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-Eli).

Predicate Device(s):

The Savannah Lumbar Percutaneous Stabilization System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These include the Synthes USS Pedicle Screw System (K022949, K010108, K010658, K994121, and K982987), DePuy Moss Miami Spinal System (K022623, K983583, K964024, K955348, and K933881), the U&I Optima Spinal System (K031585) and the Stryker Spine Xia Spinal System (K001319, K984251, and K951725).

Performance Testing:

The pre-clinical testing performed indicated that the Savannah Lumbar Percutaneous Stabilization System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neurospine Innovations and Solutions
% Silver Pine Consulting
Richard Jansen, Pharm.D.
13540 Guild Ave.
Apple Valley, MN 55124

MAR 20 2008

Re: K072116
Trade Name: Savannah Lumbar Percutaneous Stabilization System (SLPSS)
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: February 29, 2008
Received: March 4, 2008

Dear Dr. Jansen:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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): _____

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Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 General, Restorative, and Neurological Devices

510(k) Number K072116