510(k) Summary

JAN 13 2014

Date Prepared: September 26, 2013
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Trade Name: SpineSelect Polyscrew Pedicle Screw System
Product Class: Class III
Classification: 888.3070 Pedicle Screw Spinal System
Common Name: Pedicle Screw System
Product Codes: MNI, MNH, NKB
Panel Code: 87

Indications for Use:
The SpineSelect Polyscrew Pedicle Screw System is intended for immobilization and stabilization of the spine. The SpineSelect Polyscrew Pedicle Screw System is intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Device Descriptions:
The SpineSelect Polyscrew Pedicle Screw System is an implant device made from a titanium alloy TI 6Al 4V-ELI. It is to be implanted from the posterior approach. The screws are available as either solid or cannulated in diameters from 5.5-7.5 mm and in lengths from 30-55 mm. Rods are available in 5.5mm diameter either straight or pre-curved. The straight rods range in lengths from 30-400 mm, whereas the pre-curved rods range in length from 30-150mm. The system includes a screw assembly which includes a polyscrew (solid or cannulated), a saddle and tulip head, Rods are locked in place with a set screw. Associated instrumentation to complete the procedure are provided.

Predicate Device(s):
The SpineSelect Polyscrew Pedicle Screw System is substantially equivalent to the Moss Miami System (DePuy Spine) (K022623 and others), Optima Spinal System (U&I) (K031585) and Xia Spinal System (Stryker) (K001319 and others).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending and static torsion bending per ASTM F1717-10.

Conclusion:
SpineSelect concludes that the SpineSelect Polyscrew Pedicle Screw System is substantially equivalent to the predicates in regard to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2014

SpineSelect, LLC
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K133066
Trade/Device Name: SpineSelect Polyscrew Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: November 5, 2013
Received: November 6, 2013

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. 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K133066

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Prescription Use ___V____ (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 Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133066