Genesys Spine
TiLock Pedicle Screw System

JUL 2 1 2011

Special 510(k) Summary

SUBMITTED BY	Genesys Spine 1250 Capital of Texas Highway South Building Three, Suite 600 Austin, TX 78746
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	10033848
CONTACT PERSON	Brian J. Bergeron Vice President of Engineering and Regulatory Affairs Genesys Spine Phone: (512) 381-7071 Fax: (800) 817-4938
DATE PREPARED	December 10, 2010
CLASSIFICATION NAME	NKB 888.3070 - Pedicle Screw Spinal System MNI 888.3070 - Pedicle Screw Spinal System MNH 888.3070 - Pedicle Screw Spinal System
DEVICE CLASS	Class III
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	Genesys Spine TiLock Pedicle Screw System
PREDICATE DEVICE	The Genesys Spine TiLock System with Cobalt Chromium Rods was determined to be substantially equivalent to the Genesys Spine TiLock System (K100757), Globus Medical Beacon and Revere Stabilization Systems (K100788), and Medtronic Sofamor Danek TSRH Spinal System (K093058).

DEVICE DESCRIPTION

The Genesys Spine TiLock Pedicle Screw System is comprised of polyaxial screws (standard and cannulated) and monoaxial screws in various lengths and diameters, lock plugs, cross-links, tulips and rods in various lengths. The TiLock System allows the placement of either 5.5mm titanium or 5.5mm cobalt chromium rods. The TiLock cannulated polyaxial screws may be implanted via a minimally invasive technique. Manual instrumentation for implantation of the system is available for both conventional and minimally invasive procedures. The minimally invasive procedure is performed using k-wire and fluoroscopy, which allows the implanting surgeon to employ two smaller incisions rather than a longer midline incision.

The subject device is the result of modifications to the existing Genesys Spine TiLock rod system which resulted in the inclusion of a 5.5mm straight and prebent cobalt chromium rod to the system. The subject device shares the same intended use and fundamental scientific technology as the predicate device.

INDICATIONS:

The TiLock Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: 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.

TEST DATA

Test results demonstrate that the TiLock System is substantially equivalent to the predicate device.

PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):

NONCLINICAL PERFORMANCE AND CONCLUSION:

Finite element and material property analysis as well as design verification 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genesys Spine
% Mr. Brian J. Bergeron
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JUL 21 2011

Re: K103671
Trade/Device Name: Genesys Spine TiLock 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: July 01, 2011
Received: July 05, 2011

Dear Mr. Bergeron:

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,

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): K103671

Device Name: **Genesys Spine TiLock Pedicle Screw System**

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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)

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

510(k) Number K103671