



August 9, 2016

Genesys Spine
Mr. William W. Sowers
VP of Quality and Regulatory
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Re: K161914

Trade/Device Name: Genesys Spine TiLock Cortical Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: July 11, 2016
Received: July 12, 2016

Dear Mr. Sowers:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Vincent J. Devlin -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K161914

Device Name

Genesys Spine TiLock Cortical Spinal System

Indications for Use (Describe)

The TiLock Cortical Spinal 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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4. 510(K) SUMMARY

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	Primary	Secondary
Submitter's Name:	Genesys Spine	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7080	512-381-7071
Submitter's Fax:	800-817-4938	800-817-4938
Contact Name:	William W. Sowers	Brian J. Bergeron
Date Summary was Prepared:	July 11, 2016	
Trade or Proprietary Name:	Genesys Spine TiLock Cortical Spinal System	
Common or Usual Name:	Spinal Fixation System	
Classification Name:	Pedicle screw spinal system	
Classification:	Class III	
Regulation Number:	21 CFR 888.3070 – Pedicle screw spinal system	
Product Codes:	NKB, MNH, MNI	
Classification Panel:	Orthopedic Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: TiLock Pedicle Screw System (Genesys Spine - K100757) Additional Predicate(s): TiLock ² Spinal System (Genesys Spine - K103671 / K152039)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The intent of this Special 510(k) is to add new components to the currently cleared Genesys Spine TiLock Pedicle Screw System (K100757). The subject devices differ from the predicate due to the addition of a thread on the distal portion of the screw shank.

This submission presents various device configurations based on surgical approach and patient anatomy, and consists of a Genesys Spine TiLock Cortical Spinal System, which may be implanted via a conventional (open) or over-the-wire procedures.

INDICATIONS FOR USE

The TiLock Cortical Spinal 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.

TECHNICAL CHARACTERISTICS

The Genesys Spine TiLock Cortical Spinal System is comprised of polyaxial screws (solid and cannulated) in various lengths and diameters, lock screws, and rods in various lengths. The TiLock Cortical cannulated polyaxial screws may be implanted via a conventional (open) technique or with an over-the-wire technique. Manual instrumentation for implantation of the system is available for both techniques. The over-the-wire procedure is performed using k-wires and fluoroscopy. The implantable components are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F136 and cobalt-chromium-molybdenum alloy per ASTM F1537.

PERFORMANCE DATA

Not Required. Detailed FEA analysis show that a new worst-case device was not created.

CONCLUSION

The overall technology characteristics and FEA analysis data lead to the conclusion that Genesys Spine TiLock Cortical Spinal System is substantially equivalent to the Genesys Spine TiLock / TiLock² Systems (Genesys Spine - K100757 / K103671 / K152039).