November 30, 2017

Genesys Spine
Mr. Brian J. Bergeron
Vice President of Engineering
1250 Capital of Texas Highway South
Building 3 Suite 600
Austin, Texas 78746

Re: K172469
Trade/Device Name: TiLock Modular Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: November 15, 2017
Received: November 21, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172469

Device Name
Genesys Spine TiLock Modular Spinal System

Indications for Use *(Describe)*
The Genesys Spine TiLock Modular Spinal System is intended for the following indications:
The Genesys Spine TiLock Modular Spinal System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, 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 the posterior thoracic, lumbar, and sacral spine: degenerative disc disease (DDD); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, Genesys Spine TiLock Modular Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the Genesys Spine TiLock Modular Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

The Genesys Spine TiLock Modular Spinal System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the Genesys Spine TiLock Modular Spinal System is also intended for the following indications: degenerative disc disease (DDD); 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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510(K) SUMMARY

	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:	512-381-7071	512-381-7080
Submitter's Fax:	800-817-4938	800-817-4938
Contact Name:	Brian J. Bergeron	William W. Sowers
Date Summary was Prepared:	November 15, 2017	
Trade or Proprietary Name:	Genesys Spine TiLock Modular Spinal System	
Common or Usual Name:	Spinal Fixation System	
Classification:	Class II per: 21 CFR 888.3050 – Spinal interlaminal fixation orthosis 21 CFR 888.3060 – Spinal intervertebral body fixation orthosis 21 CFR 888.3070 – Thoracolumbosacral pedicle screw system	
Product Codes:	NKB, KWP, KWQ	
Classification Panel:	Orthopedic Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: TiLock^2 Spinal System (Genesys Spine - K161914) Additional Predicate(s): TiLock^2 Spinal System (Genesys Spine - K171838) TiLock Pedicle Screw System (Genesys Spine - K100757 / K103671) MAS PLIF Fixation System (NuVasive - K142737)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine TiLock Modular Spinal System is a spinal system that consists of a variety screws, lock screws, rods and associated general instruments. Implant components are available in a variety sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The TiLock Modular Spinal System implants are manufactured from titanium alloy per ASTM F136 and F1472 and Cobalt Chrome per ASTM F1537.

INDICATIONS FOR USE

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TECHNICAL CHARACTERISTICS

The Genesys Spine TiLock Modular Spinal System is comprised of inter-changeable Tulip heads, polyaxial screws (solid and cannulated) in various lengths and diameters, lock screws, and rods in various lengths. The TiLock Modular 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

Nonclinical testing was performed to demonstrate that the subject Genesys Spine TiLock Modular Spinal System is substantially equivalent to other predicate device. The following testing was performed:

- Static Compression Bending per ASTM F1717
- Dynamic Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Tulip Pull-off per ASTM F1798

The results demonstrate that the subject Genesys Spine TiLock Modular Spinal System is substantially equivalent to the predicate.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine TiLock Modular Spinal System is substantially equivalent to legally marketed predicate devices for its intended use.