DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Genesys Spine July 19, 2017
Mr. William W. Sowers
VP Quality & Regulatory
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Re: K171838
Trade/Device Name: TiLock^2 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: June 16, 2017
Received: June 20, 2017

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 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 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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171838

Device Name

TiLock^2 Spinal System

Indications for Use *(Describe)*

The TiLock^2 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 the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7080
Submitter's Fax:	800-817-4938
Contact Name:	William W. Sowers
Date Summary was Prepared:	June 16, 2017
Trade or Proprietary Name:	TiLock^2 Spinal System
Common or Usual Name:	Spinal Fixation System
Classification Name:	Thoracolumbosacral Pedicle Screw System, Spinal Interlaminal Fixation Orthosis
Classification:	Class II
Regulation Number:	21 CFR 888.3070 – Thoracolumbosacral Pedicle Screw System 21 CFR 888.3050 – Spinal Interlaminal Fixation Orthosis
Product Codes:	NKB, KWP
Classification Panel:	Orthopedic Devices Panel
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: TiLock^2 Spinal System (Genesys Spine - K152039) Additional Predicate(s): TiLock Pedicle Screw System (Genesys Spine - K100757 / K103671) LANX Spinal Fixation System (LANX - K122145)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The intent of this Special 510(k) is threefold:

1. To add the KWP product code to the system
2. Clarify the system classification is now Class II in accordance with Docket No. FDA-2014-N-1205
3. Add / revise system instrumentation

The Genesys Spine TiLock^2 Spinal System is offered in polyaxial screws (solid and cannulated) and monoaxial screws in various lengths and diameters, offset connectors, washers, hooks, rod-to-rod connectors, lock screws, crosslinks, and rods in various lengths and materials.

INDICATIONS FOR USE

The TiLock^2 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 the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

TECHNICAL CHARACTERISTICS

The Genesys Spine TiLock^2 Spinal System is comprised of polyaxial screws (solid and cannulated) and monoaxial screws in various lengths and diameters, offset connectors, washers, hooks, rod-to-rod connectors, lock screws, crosslinks, and rods in various lengths. The TiLock^2 System only allows the placement of 5.5mm titanium or cobalt chromium rods. The TiLock^2 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 TiLock^2 tulips are available in three (3) configurations: standard, break off and extended tab. The extended tab tulips are only assembled utilizing cannulated screws, as it is intended to facilitate screw insertion during minimally invasive procedures. The TiLock^2 implantable components are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F136 and cobalt-chromium-molybdenum alloy per ASTM F1537.

The Genesys Spine TiLock^2 Spinal System implants remain unchanged from their previously cleared configuration outlined in K100757, K103034, and K152039. As such no new testing or analysis is required. In addition, since all of the implants have been previously cleared they do not present any new risks to mechanical strength or performance. The devices in the TiLock^2 Spinal System are utilized in the same manner as the predicate devices.

PERFORMANCE DATA

Not Required. There was no change to the cleared system implants or the manner in which they are used. The instrument additions mimic previously cleared instruments with minor alterations.

CONCLUSION

The technology and characteristics of the TiLock^2 Spinal System remains unchanged. Laminar hooks were previously cleared per K152039. This submission adds the KWP product code corresponding to spinal interlaminal fixation orthosis. The added system instrumentation are all derivatives of previously cleared system devices and do not add any new technology or novel characteristics. As a result, the modified TiLock^2 Spinal System is considered substantially equivalent to the previous Genesys Spine TiLock / TiLock^2 Systems (Genesys Spine - K100757 / K103671 / K152039) as well as the LANX Spinal Fixation System (K122145).