



October 24, 2019

Genesys Spine
Chloe Lance
Quality Assurance Engineer II
1250 Capital of Texas Highway South
Building 3 Suite 600
Austin, Texas 78746

Re: K192678

Trade/Device Name: Genesys Spine Binary® Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 23, 2019
Received: September 26, 2019

Dear Chloe Lance:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Ronald Jean
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192678

Device Name

Genesys Spine Binary® Lumbar Plate System

Indications for Use (Describe)

The Genesys Spine Binary Lumbar Plate System is indicated as additional support during fusion via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1 -L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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

Submitter's Name:	Genesys Spine	
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746	
Contact Name:	Chloe Lance (Primary)	William W. Sowers (Secondary)
Submitter's Telephone:	512-381-7089	512-381-7080
Submitter's Fax:	512-381-7076	512-381-7076
Date Summary was Prepared:	September 23, 2019	
Trade or Proprietary Name:	Genesys Spine Binary® Lumbar Plate System	
Common or Usual Name:	Spinal Intervertebral Body Fixation Orthosis	
Classification Name:	Class II per 21 CFR §888.3060	
Classification:	Class II	
Regulation Number:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis	
Product Codes:	KWQ	
Classification Panel:	Orthopedic and Rehabilitation Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Binary Lumbar Plate System (Genesys Spine – K173885)	

PURPOSE OF THE 510(K)

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

1. Add additional Lumbar Sacral Plates to the Binary Lumbar Plate System
2. Add / revise system instrumentation

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Binary Lumbar Plate System consists of an assortment of plates and screws. The Binary Lumbar Plate System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

Implant components are available in a variety of sizes to suit the individual pathology and anatomical conditions. The Genesys Spine Binary Lumbar Plate System implants are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F136.

TECHNICAL CHARACTERISTICS

The Genesys Spine Binary Lumbar Plate System is comprised of multiple sizes of plates and screws that are inserted via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels of the lumbar spine. The system is designed to provide additional support during fusion. It has equivalent technological characteristics to its predicate device through comparison in areas including intended use, material, composition, principles of operation and design.

INDICATIONS FOR USE

The Genesys Spine Binary Lumbar Plate System is indicated as additional support during fusion via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1 -L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

PERFORMANCE DATA

Engineering analysis was performed on the subject devices and it was determined that a new worst-case was not created, therefore additional testing was not required. The instrument additions mimic previously cleared instruments with minor alterations.

CONCLUSION

The overall technological characteristics have led to the conclusion that the additional devices in the subject submission do not create a new worst case. The system remains as safe and as effective and performs as well or better than the current legally marketed device. As a result, the modified Genesys Spine Binary Lumbar Plate System is considered substantially equivalent to the previously cleared Genesys Spine Binary Lumbar Plate System (Genesys Spine – K173885).