April 3, 2018

Genesys Spine
William W. Sowers
VP Quality & Engineering
1250 South Capital of Texas Highway, Building 3 Suite 600
Austin, Texas 78746

Re: K173885
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: March 8, 2018
Received: March 9, 2018

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.

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,

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)*

K173885

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 stenos is, 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
Submitter's Telephone:	512-381-7080
Submitter's Fax:	800-817-4938
Contact Name:	William W. Sowers
Date Summary was Prepared:	March 13, 2018
Trade or Proprietary Name:	Genesys Spine Binary Lumbar Plate System
Common or Usual Name:	Spinal Fixation System
Classification:	Class II per: 21 CFR 888.3060 – Spinal intervertebral body fixation orthosis
Product Codes:	KWQ
Classification Panel:	Orthopedic Devices Panel
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Stryker LITe Plate System (K142699) Additional Predicate(s): Spinal USA AccuFit Plate System (K091044), Synthes Anterior Tension Band System (K022791), Depuy Aegis Anterior Lumbar Plate (K052546), Synthes TSLP Thoracolumbar Plate (K020244)

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 of the patient. The Genesys Spine Binary Lumbar Plate System implants are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F136.

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.

TECHNICAL CHARACTERISTICS

As established in this submission, the Genesys Spine Binary Lumbar Plate System was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including intended use, material composition, principles of operation and design.

PERFORMANCE DATA

Nonclinical testing was performed to demonstrate that the subject Genesys Spine Binary Lumbar Plate System is substantially equivalent to other predicate devices.
The following testing was performed:

- Static Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Dynamic Compression Bending per ASTM F1717

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Binary Lumbar Plate System is substantially equivalent to legally marketed predicate devices for intended use, material composition, principles of operation, and design.