August 29, 2018

Genesys Spine
Benjamin Keller
Product Development Engineer
1250 Capital of Texas Highway South
Building 3 Suite 600
Austin, Texas 78746

Re: K181295
Trade/Device Name: Genesys Spine AIS-C Cervical Stand-Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: July 26, 2018
Received: July 30, 2018

Dear Mr. Keller:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Melissa Hall -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)*
K181295

Device Name
Genesys Spine AIS-C Cervical Stand-Alone System

Indications for Use *(Describe)*
The Genesys Spine Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Genesys Spine Cervical Stand-Alone System is to be used with autogenous bone graft and implanted via an anterior approach.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	Benjamin V. Keller (Primary)	William W. Sowers (Secondary)
Submitter's Telephone:	512-381-7093	512-381-7080
Submitter's Fax:	800-817-4938	800-817-4938
Date Summary was Prepared:	August 23, 2018	
Trade or Proprietary Name:	Genesys Spine AIS-C Cervical Stand-Alone System	
Common or Usual Name:	Intervertebral Body Fusion Device, Cervical	
Classification Name:	Intervertebral Fusion Device With Integrated Fixation, Cervical	
Classification:	Class II per 21 CFR §888.3080	
Regulation Number:	21 CFR 888.3080	
Product Codes:	OVE	
Classification Panel:	Orthopedic Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: LDR Spine Cervical Interbody Fusion System – ROI-C (K113559) Additional Predicate Devices: Genesys Spine AIS-C Anchored Cervical Interbody Fusion System (K180056) Genesys Spine Apache® Anchored Cervical Interbody Fusion System (K152099) Genesys Spine Apache® IBFD System (K103034)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine AIS-C Cervical Stand-Alone System includes PEEK interbodies and titanium interbodies, which utilize an integrated titanium alloy locking mechanism. Both PEEK interbodies and titanium interbodies are to be anchored to patient anatomy via two (2) titanium alloy bone anchors.

The integrated fixation anchors may not provide adequate stability for all situations. The Surgeon should consider the appropriate fixation required for each patient and determine if additional supplemental fixation (e.g. anterior plate, posterior cervical screws) may be needed.

INDICATIONS FOR USE

The Genesys Spine Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Genesys Spine Cervical Stand-Alone System is to be used with autogenous bone graft and implanted via an anterior approach.

TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Genesys Spine AIS-C Cervical Stand-Alone System is comprised of two versions of interbodies, each of which are secured by integrated fixation Anchors. The interbodies are available in a PEEK configuration with tantalum markers or in a titanium alloy version. Both versions use the same integrated titanium alloy locking mechanism. The interbodies are to be available in several footprints, configurations, and heights. The titanium alloy cervical bone Anchors provide integrated fixation for the system and are to be offered in various lengths. The bone Anchors are deployed through the channels in the interbody and embed into the adjacent cervical vertebrae.

The PEEK interbody devices are made of polyether-ether-ketone (Invibio's PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the PEEK implants contain tantalum markers per ASTM F560 to assist the surgeon with proper placement of the device in the disk space. The titanium alloy interbody devices, anchor locking mechanism, and the bone anchor components are manufactured from medical grade Ti6Al-4V ELI titanium alloy per ASTM F136.

The subject and predicate devices are based on the following same technological elements:

- Integrated fixation Anchors provide additional biomechanical support to the interbody
- Devices are offered in similar sizes and shapes (parallel, lordotic, and convex) which provide surgeons options to suit the patient's anatomy
- Implants materials are identical: PEEK, Titanium 6Al-4V ELI alloy, and Tantalum
- Use of a single inserter instrument to position the interbodies and deploy the Anchors

PERFORMANCE DATA

The predetermined pass-fail criterion was that the mechanical test results for the Genesys Spine Cervical Stand-Alone System be equivalent to (or greater than) previously cleared interbody fusion systems. Prior to performing mechanical testing, all possible configurations of the AIS-C Cervical Stand-Alone System constructs were analyzed in order to determine the worst case to be used for testing.

The Genesys Spine AIS-C Cervical Stand-Alone System was tested in static and dynamic axial compression, compressive-shear, and torsion per ASTM F2077-11, static subsidence per ASTM F2267-04, expulsion testing, and cadaver testing. The system was also tested to determine the force to overcome the locking mechanism under worst-case conditions. These results were compared to the predicate devices to establish substantial equivalence.

CONCLUSION OF NON-CLINICAL TESTS:

The overall technological characteristics and mechanical performance data lead to the conclusion that the Genesys Spine AIS-C Cervical Stand-Alone System is substantially equivalent to the LDR Spine Cervical Interbody Fusion System – ROI-C (K113559), the Genesys Spine AIS-C Anchored Cervical Interbody Fusion System (K180056), the Genesys Spine Apache® Anchored Cervical Interbody Fusion System (K152099), and the Genesys Spine Apache® IBFD System (K103034).