January 8, 2020

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

Re: K191489
Trade/Device Name: Genesys Spine 3DP Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: December 11, 2019
Received: December 13, 2019

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/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,

Brent L. Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K191489

Device Name
Genesys Spine 3DP Cervical Interbody Fusion System

Indications for Use *(Describe)*

When used with the internal fixation and as a stand-alone system:
The Genesys Spine 3DP Cervical Interbody Fusion 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 3DP Cervical Interbody Fusion System is to be used with autogenous bone graft and implanted via an anterior approach.

When used without the internal fixation:
The Genesys Spine 3DP Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (i.e. cleared cervical plating system) and with autograft to facilitate fusion. These patients should have had six weeks of non-operative treatment.

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:	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:	December 31st, 2019	
Trade or Proprietary Name:	Genesys Spine 3DP Cervical Interbody 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, ODP	
Classification Panel:	Orthopedic Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Genesys Spine AIS-C Cervical Stand-Alone System (Genesys Spine - K181295) Additional Predicate Devices: 3DP Lumbar Interbody System (Genesys Spine – K182987) EIT Cellular Titanium® Cervical & Lumbar Cages (Emerging Implant Technologies – K170503) Apache® Interbody Fusion System (Genesys Spine - K103034) Apache® Cervical Interbody Fusion System (Genesys Spine - K150812) LDR Spine Cervical Interbody Fusion System (LDR Spine - K091088)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine 3DP Cervical Interbody System includes 3D-Printed (3DP) titanium interbodies. The 3DP Cervical Interbody System offers a stand-alone version as well as a traditional (Regular) interbody that requires supplemental fixation. The version that utilizes integrated fixation may be used as a stand-alone cervical device that is implanted with two (2) titanium alloy anchors. All interbodies are made from Ti-6Al-4V ELI titanium alloy. The stand-alone version includes an integrated locking mechanism and various sizes of anchors which are all manufactured from Ti-6Al-4V ELI titanium alloy.

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

When used with the integrated fixation and as a stand-alone system:

The Genesys Spine 3DP Cervical Interbody Fusion 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 3DP Cervical Interbody Fusion System is to be used with autogenous bone graft and implanted via an anterior approach.

When used without the integrated fixation:

The Genesys Spine 3DP Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (i.e. cleared cervical plating system) and with autograft to facilitate fusion. These patients should have had six weeks of non-operative treatment.

TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Genesys Spine 3DP Cervical Interbody System was compared to the predicate systems and the designs, materials, features, functions, and intended uses were found to be substantially the same.

NON-CLINICAL PERFORMANCE EVALUATION

Performance evaluations were conducted on constructs representing the worst-case components (including static compression, static torsion, static compression shear, dynamic compression, dynamic torsion, dynamic compression shear [in accordance with ASTM F2077], subsidence [in accordance with ASTM F2267], expulsion testing, and cadaver testing. The system was also tested to determine the force to overcome the locking mechanism under worst-case conditions. The Genesys Spine 3DP Cervical Interbody System was found to be substantially the same as predicate devices.

CONCLUSION OF NON-CLINICAL TESTS:

The overall technological characteristics and mechanical performance data demonstrate that the Genesys Spine 3DP Cervical Interbody System is substantially equivalent to the Genesys Spine AIS-C Anchored Cervical Stand-Alone System (K181295), the EIT Cellular Titanium® Cervical Cages (K170503), the Genesys Spine Apache® Cervical Interbody Fusion System (K150812), and the Genesys Spine Apache® IBFD System (K103034).