December 13, 2023

Genesys Spine
Andrew Davison
Senior Vice President of Quality and Regulatory
1250 S. Capital of Texas Highway Building 3, Suite 600
Austin, Texas 78746

Re: K233594
Trade/Device Name: Genesys Spine 3DP AIS-C II Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: November 8, 2023
Received: November 8, 2023

Dear Andrew Davison:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Showalter -S

Brent Showalter, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233594

Device Name
Genesys Spine 3DP AIS-C II Cervical Interbody System

Indications for Use *(Describe)*

When used with the integrated fixation and as a stand-alone system:
The Genesys Spine 3D Printed AIS-C II 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 3D Printed AIS-C II 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 3D Printed AIS-C II 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.

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

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510(k) Summary

Prepared on: 2023-11-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Genesys Spine
Applicant Address	1250 S. Capital of Texas Highway Building 3, Suite 600 Austin TX 78746 United States
Applicant Contact Telephone	512-431-7255
Applicant Contact	Mr. Andrew Davison
Applicant Contact Email	andrew.davison@genesysspine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Genesys Spine 3DP AIS-C II Cervical Interbody System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Regulation Number	888.3080
Product Code	OVE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191489	Genesys Spine 3DP Cervical Interbody System	OVE

Device Description Summary

21 CFR 807.92(a)(4)

GENERAL OVERVIEW

The Genesys Spine 3DP AIS-C II 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 interbody that utilizes supplemental fixation may be used as a stand-alone cervical device that is implanted with two (2) titanium alloy anchors. This version includes an integrated cam lock mechanism and various sizes of anchors. The cam lock mechanism may be used as a secondary aid in keeping the anchors from backing out of the interbody and vertebral bodies after anchor deployment. After anchor deployment, in order to engage the cam lock, a cam lock key instrument is used to turn the lock (counterclockwise direction) from an open to closed position. When closed, the wings of the cam lock slide over the anchor channels and provide a backing cover for the anchor and anchor channels.

All interbodies and anchors are made from Ti-6Al-4V ELI titanium alloy. The cam lock is made out Ti-6Al-4V ELI titanium alloy with a PEEK washer.

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.

PRODUCT SPECIFICATIONS AND DIMENSIONS

Product and engineering specifications, and engineering drawings for all implants and system specific instruments are provided as attached.

SURGICAL TECHNIQUE
A detailed surgical technique is available as attached. The surgical technique defines the surgical technique for implants, anatomical location of use, various user interfaces, how the device interacts with other devices, and how the device interacts with the patient.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

When used with the integrated fixation and as a stand-alone system:
The Genesys Spine 3D Printed AIS-C II 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 3D Printed AIS-C II 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 3D Printed AIS-C II 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use remain the same.

Technological Comparison

21 CFR 807.92(a)(6)

The primary predicate device for this 510(k) is the Genesys Spine 3DP AIS-C Cervical Standalone Interbody Fusion System (K191489). Both systems offer cervical anchored interbody systems with an OVE product classification. A locking mechanism to secure the integrated fixation anchors are used in both systems. The indications for use statements are identical to the predicate. The principles of operation are the same. The anchoring technology is identical and testing shows that the subject interbody device is as effective as the primary predicate device. The footprints, sizes, and overall geometry are the same. In addition, non-clinical performance (bench) testing shows the 3DP AIS-C II Cervical Interbody Fusion System has the equivalent or better capabilities compared to the primary predicate system or market competitors.

The subject devices differ from the primary predicate Genesys Spine Interbody System in the following characteristics:
• Locking Mechanism - titanium alloy cam lock with PEEK washer
• Interbody Lock Recess Geometry
• Addition of a 10 degree lordosis angle for the Lordotic Interbody
• Anchor Geometry

In order to clarify the details behind this analysis each of the differences from the primary predicate was evaluated in the following manner:
• Locking Mechanism: The locking mechanism used on the 3DP AIS-C II Cervical Interbody Fusion System was modified from a titanium alloy flange lock (predicate) to a titanium alloy with PEEK washer cam lock (subject). Relative to previous locks used on predicate interbodies the cam lock provides greater Anchor push-out strength and a more intuitive user interface.
o Anchor Push-Out testing was conducted, and the results proved superior to predicates.
o Biocompatibility analysis was performed for both PEEK and titanium alloy along with the mating feature of the cam lock. The cam lock does not introduce any new worst-case in any criteria and is safe and effective.
o Sterilization/Cleaning analysis was performed on the mating feature of the titanium cam lock and PEEK washer. The cam lock does not introduce any new worst-case in any criteria and is deemed safe and effective.
o Design Validation testing was performed, and user feedback confirmed superior usability to predicates.
• Interbody Lock Recess Geometry: The recess geometry for mating the lock with the interbody was modified to allow assembly of the new locking mechanism.

o The mechanical performance of the system was evaluated in static compression, static torsion, static compression shear, dynamic compression, dynamic torsion, and dynamic compression shear in accordance with ASTM F2077. Test results indicated the revised interbody did not pose additional risks to safety and effectiveness of the devices.
• Addition of 10 Degree Lordotic Interbody: In order to serve a larger range of the population and user demographic an explicit 10 degree lordotic interbody was created.
o Finite Element Analysis was conducted, and the results proved that the 10 degree lorodtic interbody did not introduce any new worst-case in regards to mechanical stresses and standardized testing and was still superior to predicate.
o Design Validation testing was performed, and user feedback confirmed superior usability to predicates.
• Anchor Geometry: The anchor geometry remains almost identical to what was released under K191489. The modification to the anchor was the addition of a small interference ramp up on the side of the anchor. This was done in order to provide perceptual indication that the anchor was secure, but also provide tactile feedback that the anchor was not loose within the interbody channel.
o Anchor Push-Out testing was conducted, and the results proved superior to predicates.
o Design Validation testing was performed, and user feedback confirmed superior usability to predicates.

All interbody devices, which all have the ACC- prefix, are the same as previously cleared by the predicate 510(k) submission: K191489. The design of the integrated locking mechanism has been improved to increase anchor push-out forces and physician usability. The cervical Anchors, which all have the GAC- prefix, have been updated slightly from the previously cleared 510(k) submission K191489.

The Genesys Spine 3DP AIS-C II Cervical Interbody Fusion System was compared to the predicate systems and the designs, materials, features, functions, intended uses and overall technology were found to be substantially equivalent. As a result of this analysis, the system differences would not impact safety or effectiveness. This analysis can be found in the substantial equivalence comparison attachment.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

N/A