February 7, 2025

Genesys Spine
Mr. Bill Sowers
Chief Technical Officer
1250 South Capital of Texas Highway
Building 3, Suite 600
Austin, Texas 78746

Re: K242483
Trade/Device Name: Genesys Spine AIS-C II Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: January 2, 2025
Received: January 7, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Katherine D. Kavlock -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242483

Device Name

Genesys Spine AIS-C II Cervical Interbody Fusion System

Indications for Use *(Describe)*

When used with the integrated fixation and as a standalone system:
The Genesys Spine AIS-C II Cervical Interbody Fusion System is a standalone 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 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 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.

510(k) #: K242483

510(k) Summary

Prepared on: 2025-02-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Genesys Spine
Applicant Address	1250 South Capital of Texas Highway Building 3, Suite 600 Austin TX 78746 United States
Applicant Contact Telephone	954-557-8288
Applicant Contact	Mr. Bill Sowers
Applicant Contact Email	bill.sowers@genesysspine.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181295	Genesys Spine AIS-C Cervical Stand-Alone System	OVE
K233594	Genesys Spine 3DP AIS-C II Cervical Interbody System	OVE

Device Description Summary

21 CFR 807.92(a)(4)

GENERAL OVERVIEW

The Genesys Spine AIS-C II Cervical Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy. The AIS-C II System has two interbody options: Regular or Standalone.

The Regular Cervical Interbody System does not require the use of Anchors but is designed for use with supplemental fixation (i.e., cleared cervical plating system).

The Standalone Cervical Interbody System requires the use of Anchors for integrated fixation. 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, a cam lock key is used to turn the lock (counterclockwise) to engage the cam lock and secure the anchors. When engaged (closed), the wings of the cam lock cover the anchor channels and provide a backing plate for the anchors.

The subject and predicate devices are based on the same technological characteristics:
Integrated fixation anchors provide additional biomechanical support to the interbody.
Implant materials are identical: PEEK, Titanium 6AL-4V ELI alloy, and tantalum.
A single inserter can be used to position the interbody and deploy the anchors.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

When used with the integrated fixation and as a standalone system:
The Genesys Spine AIS-C II Cervical Interbody Fusion System is a standalone 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 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 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)

As defined in 21 CFR 814.20(b)(3)(i), the subject device, primary, and reference predicate devices are all indicated for use to treat the same disease or condition (degenerative disc disease ("DDD") with accompanying radicular symptoms at one level from C2-T1). The subject device and predicate devices are also indicated for the same patient population (skeletally mature patients having had six weeks of non-operative treatment).

Technological Comparison

21 CFR 807.92(a)(6)

Materials: Both the subject device and the primary predicate device are manufactured from the same materials. Both interbodies are comprised of a polyetheretherketone ("PEEK" per ASTM F2026) interbody with tantalum markers (per ASTM F560) to assist the surgeon with proper placement of the device in the disc space. The interbodies also contain a titanium alloy locking mechanism. The Standalone Cervical Interbody System is also coupled with two (2) titanium alloy anchors for integrated fixation. All anchors and the cam lock are made from Ti-6Al-4V ELI titanium alloy (per ASTM F136).

The instrumentation for the subject device and predicate device utilize stainless steel, titanium, polyphenylsulfone, and silicone. No new identifiable risks have been introduced.

Sterility: The subject device, primary, and reference predicate devices are all provided non-sterile. No new identifiable risks have been introduced.

Manufacturing: The subject device and predicate utilize subtractive techniques with an established history of medical device implant/ instrumentation fabrication. No new identifiable risks have been introduced.

Design: Both the subject device and predicate device implants/instrumentation have the same design characteristics. No new identifiable risks have been introduced.

Principles of Operation: Both the subject device and predicate device systems have the same principles of operation. No new identifiable risks have been introduced.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing was performed as support for this submission per guidance document "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device - Guidance for Industry and FDA Staff". Consensus standards used include:

ASTM F2267-22: Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

ASTM F2077-22: Test Methods for Intervertebral Body Fusion Devices

ASTM F1877-16: Standard Practice for Characterization of Particles

ASTM F04.25.02.02 (Draft): Static Push-out Test Method for Intervertebral Body Fusion Devices

ASTM F3292-19: Standard Practice for Inspection of Spinal Implants Undergoing Testing

ISO 23089-2 First edition 2021-05: Implants for surgery - Preclinical mechanical assessment of spinal implants and particular requirements - Part 2: Spinal intervertebral body fusion devices

Clinical testing is not required.

Nonclinical mechanical testing demonstrates that the subject device either exceeds performance data referenced by the predicate submission or aggregated mechanical test data from IBFDs previously cleared by the U.S. Food and Drug Administration through the 510(k) process. Data of previously cleared devices is cited in "Mechanical performance of cervical intervertebral body fusion devices: A systematic analysis of data submitted to the Food and Drug Administration" (Journal of Biomechanics, 2007) and ISO 23089-2:2021 Implants for surgery - Preclinical mechanical assessment of spinal implants and particular requirements - Part 2: Spinal intervertebral body fusion devices. These results demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K181295) or currently cleared devices.