August 21, 2026

Osseus Fusions Systems, LLC
Jonathan Rosen
Director of Compliance and Regulatory
1931 Greenville Avenue, Suite 200
Dallas, Texas 75206

Re: K261882
Trade/Device Name: Pisces-SC Standalone Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: June 26, 2026
Received: June 26, 2026

Dear Mr. Rosen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261882

Please provide the device trade name(s).

Pisces-SC Standalone Cervical Interbody System

Please provide your Indications for Use below.

The Pisces-SC Standalone Cervical Interbody System is a standalone anterior cervical interbody fusion device indicated for use at one or two contiguous levels in the cervical spine (C2-T1) in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1 (DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudoarthrosis, and failed previous fusion. The Pisces-SC Standalone Cervical Interbody System is to be used with autogenous and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone graft to facilitate fusion. The Pisces-SC Standalone Cervical Interbody System is intended to be used with or without two screws and/or anchors which accompany the interbodies.

When used with two screws, the devices are intended for standalone use (requiring no supplemental fixation) at one or two contiguous levels.

When used with one or more anchors or without integrated fixation (screws / anchors), these devices require additional supplemental fixation (i.e. anterior cervical plate or posterior cervical screws).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

XI. 510(k) Summary

Submitted By:

Submitted By:	Osseus Fusion Systems 1931 Greenville Ave. Suite 200 Dallas, TX 75206
Date:	06/26/2026
Contact Person:	Jonathan Rosen, Director of Compliance & Regulatory
Contact Telephone:	(888) 330-5960 ext. 285
Contact Fax:	(866) 766 8978
Device Trade Name:	Pisces-SC Standalone Cervical Interbody System
Device Classification Name:	Intervertebral Fusion Device With Integrated Fixation, Cervical
Device Classification	Class II
Reviewing Panel	Orthopedic
Product Code	OVE
Primary Predicate	**(K233594)** Genesys Spine 3DP AIS-C II Cervical Interbody System
Additional Predicates	• **(K200543)** NEXXT MATRIXX® Stand Alone Cervical-Turn Lock (-TL) System • **(K223869)** ChoiceSpine Blackhawk Ti Cervical Spacer System • **(K253876)** Globus Hedron C-MIS

Device Description:

The Pisces-SC Standalone Cervical Interbody System is a standalone interbody fusion device for the cervical spine that may be used with two titanium alloy screws or anchors which accompany the interbodies. When used with screws, these devices are standalone interbody fusion devices. When used with anchors or without screws, these devices are intended for use with supplemental fixation (e.g. anterior cervical plate or posterior cervical screws). The Pisces-SC interbodies are available in multiple sizes and are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The interbodies are single use devices, which are sterilized via gamma radiation and are provided to the user in sterile packages. The screws and anchors are single-use devices which are available in multiple sizes and are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The locking plates are single-use devices which are available in a single size and are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.The instruments used to insert the implants are manufactured from medical grade stainless steel. The screws, anchors, locking plates, and instruments are provided non-sterile and must be sterilized prior to use in a supplied re-usable tray for steam sterilization. The sterilization parameters have been validated to achieve a SAL of 10^{-6}.

The Pisces-SC Standalone Cervical Interbody System contains components manufactured using traditional machining methods and additive manufacturing methods.

The Pisces-SC interbodies are available in three different footprints (14x12mm, 16x13mm, 18x14mm), heights ranging from 5mm to 12mm in 1mm increments, and lordotic angles ranging from 0° to 12°. The Pisces-SC screws and anchors have a neutral trajectory angle of 35° cephalad-caudal. The Pisces-SC locking plate assembly is comprised of a plate that prevents backout of the fixation components (screws or anchors) with an integrated central M2x0.4 bolt that affixes the locking plate assembly to the interbody. The Pisces-SC locking plate assembly is available in one size that is compatible

with all interbody configurations. The locking plate is 4.25mm tall and tapers down to 3.4mm over a 12mm width. The back of the plate has features that key into the interbody to create a secure interface. The plate also has two through-holes that allow for engagement of the locking plate inserter.

The uninterrupted endplate graft contact area varies based on the footprint of the device. The interbody with the smallest footprint and shortest height has approximately 123mm² of uninterrupted endplate graft contact area and approximately 307mm³ of uninterrupted graft volume. On the spacer there is a centrally located threaded hole to connect with the inserter and locking plate.

Intended Use:

The Pisces-SC Standalone Cervical Interbody System is a standalone anterior cervical interbody fusion device indicated for use at one or two contiguous levels in the cervical spine (C2-T1) in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1 (DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudoarthrosis, and failed previous fusion. The Pisces-SC Standalone Cervical Interbody System is to be used with autogenous and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone graft to facilitate fusion. The Pisces-SC Standalone Cervical Interbody System is intended to be used with or without two screws and/or anchors which accompany the interbodies.

When used with two screws, these devices are intended for standalone use (requiring no supplemental fixation) at one or two contiguous levels.

When used with one or more anchors or without integrated fixation (screws / anchors), these devices require additional supplement fixation (i.e. anterior cervical plate or posterior cervical screws)..

Summary of Technological Characteristics:

Pisces-SC Standalone Cervical Interbody System and the predicates have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Please see Table 11a Below for a comparison of the devices.

Summary of Technological Characteristics:
Table 11a: Technological Characteristics Comparison

Feature	Subject Device:	Primary Predicate:	Comparison
Regulation	888.3080	888.3080	Equivalent
Product Code	OVE	OVE	Equivalent
Indications for Use	The Pisces-SC Standalone Cervical Interbody System is a standalone anterior cervical interbody fusion device indicated	When used with the integrated fixation and as a stand-alone system: The Genesys Spine 3D Printed AIS-C II	Subject Device Substantially Equivalent to Secondary Predicate

	for use at one or two contiguous levels in the cervical spine (C2-T1) in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1 (DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudoarthrosis, and failed previous fusion. The Pisces-SC Standalone Cervical Interbody System is to be used with autogenous and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone graft to facilitate fusion. The Pisces-SC Standalone Cervical Interbody System is intended to be used with or without two screws and/or anchors which accompany the interbodies. When used with two screws, these devices are intended for standalone use	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	

	(requiring no supplemental fixation) at one or two contiguous levels. When used with one or more anchors or without integrated fixation (screws / anchors), these devices require additional supplement fixation (i.e. anterior cervical plate or posterior cervical screws).	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.	
Device Description	The Pisces-SC Standalone Cervical Interbody System is a standalone interbody fusion device for the cervical spine that may be used with two titanium alloy screws or anchors which accompany the interbodies. When used with screws, these devices are standalone interbody fusion devices. When used with anchors or without screws, these devices are intended for use with supplemental fixation (e.g. anterior cervical plate or posterior cervical screws). The Pisces-SC interbodies are available in multiple sizes and are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The interbodies are single use devices which are sterilized via gamma radiation and are provided to the user in sterile packages. The screws, anchors, and locking plates are	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	Substantially Equivalent

	available in multiple sizes and are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The instruments used to insert the implants are manufactured from medical grade stainless steel. The screws, anchors, locking plates, and instruments are provided non-sterile and must be sterilized prior to use in a supplied re-usable tray for steam sterilization. The sterilization parameters have been validated to achieve a SAL of 10^{-6}. The Pisces-SC Standalone Cervical Interbody System contains components manufactured using traditional machining methods and additive manufacturing methods. The Pisces-SC screws, anchors, locking plates, and instruments are manufactured using traditional machining methods.	(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 of 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.	
Interbody Heights	5-12 mm in 1 mm increments	5-12mm in 1mm increments	Equivalent
Footprints	14x12 mm, 16x13 mm, 18x14 mm	14x12 mm, 17x14 mm	Substantially Equivalent
Lordotic Angles	0°, 6°, 12°	0° - 10°	Substantially Equivalent
Standalone Fixation Technology	Yes	Yes	Equivalent
Screw Diameters	Ø 3.5 mm and Ø4.0 mm	N/A – Device uses Anchors	Subject Device Substantially

			Equivalent to Secondary predicate
Screw Lengths	10-20 mm in 2 mm increments	N/A – Device uses Anchors	Subject Device Substantially Equivalent to Secondary predicate
Screw Types	Self-Drilling, Self-Tapping	N/A – Device uses Anchors	Subject Device Substantially Equivalent to Secondary predicate
Anchor Diameter	Ø3.9 mm	Not Publicly Available	Substantially Equivalent
Anchor Lengths	11.4 mm, 12.35 mm	Not Publicly Available	Substantially Equivalent
Materials	Ti-6Al-4V ELI per ASTM F3001 and ASTM F136	Ti-6Al-4V ELI per ASTM F3001 and ASTM F136	Equivalent

Non-clinical Testing:

Mechanical testing was performed on the Osseus Pisces-SC Standalone Cervical Interbody System in static and dynamic compression per ASTM F2077, static and dynamic compression shear per ASTM F2077, static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267, and expulsion testing. The results support that the subject device is substantially equivalent to the predicates.

Conclusion:

Based on Indications for use, technological characteristics, and comparison with the predicate devices, the subject device has demonstrated substantial equivalence.