May 6, 2022

Osseus Fusion Systems
% Daniel Johnson
Regulatory Engineer
Jalex Medical LLC
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K213935
Trade/Device Name: PISCES™-SA Standalone ALIF Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX, PHM

Dear Daniel Johnson:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 6, 2022. Specifically, FDA is updating this SE Letter to correct the product code as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, Brent.Showalter@fda.hhs.gov.

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

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Trade/Device Name: PISCES™-SA Standalone ALIF Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX, PHH
Dated: April 26, 2022
Received: April 27, 2022

Dear Daniel Johnson:

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 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)*
K213935

Device Name
PISCES™-SA Standalone ALIF Interbody System

Indications for Use *(Describe)*
PISCES™-SA ALIF Spacers (Standalone Use, With Integrated Fixation)
The PISCES™-SA (Standalone) ALIF Interbody System are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PISCES™-SA (Standalone) ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.
• PISCES™-SA Used With Screws:
When used with three (3) screws, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels.

Hyperlordotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels.

• PISCES™-SA Used With Anchors
When used with three (3) anchors, these devices can be used as interbody fusion devices at 1 or 2 levels and must always be used with supplemental fixation.

PISCES™ ALIF Spacers (Without Integrated Fixation)
PISCES™ ALIF Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PISCES™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

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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OSSEUS™

510(k) Summary

Submitted By: Osseus Fusion Systems
1931 Greenville Ave.
Suite 200
Dallas, TX 75206

Date: 12/14/21

Contact Person: Daniel Johnson, Regulatory Engineer
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: PISCES™-SA STANDALONE ALIF Interbody System
Device Classification Name: Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: OVD, MAX, PHM
Predicate Device: K191391 - Globus HEDRON Lumbar Spacers
Additional Predicates: K181347 - Osseus ARIES Lumbar Interbodies
K153495 - Zimmer ROI-A ALIF Cage System
K203742 - Alphatec IdentiTi™ ALIF Standalone Interbody System
K192121 - Black Diamond Pedicle Screw System

The predicate devices have not been subject to any design related recalls.

Device Description:
PISCES™-SA Standalone ALIF Interbody System is an interbody fusion device for the lumbar spine that may be used with three titanium alloy screws or anchors which accompany the implants. 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. facet screws or posterior fixation). The PISCES™-SA interbodies are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The spacers are available in multiple sizes. The spacers 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 manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and must be sterilized prior to use. The instruments used to insert the cage are manufactured from medical grade stainless steel and must be sterilized prior to use. The screws, anchors, locking plates, and instruments are supplied in a re-usable tray for steam sterilization.

Intended Use:

PISCES™-SA ALIF Spacers (Standalone Use, With Integrated Fixation)

The PISCES™-SA (Standalone) ALIF Interbody System are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and

have had at least six (6) months of non-operative treatment. PISCES™-SA (Standalone) ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

- PISCES™-SA Used With Screws:
  When used with three (3) screws, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels.

  Hyperlordotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels.

- PISCES™-SA Used With Anchors
  When used with three (3) anchors, these devices can be used as interbody fusion devices at 1 or 2 levels and must always be used with supplemental fixation.

PISCES™ ALIF Spacers (Without Integrated Fixation)

PISCES™ ALIF Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PISCES™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Summary of Technological Characteristics:

PISCES™-SA Standalone ALIF 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 1 Below for a comparison of the devices. The Globus HEDRON information was gathered from the system's surgical technique and marketing information.

Summary of Technological Characteristics:

Table 1: Technological Characteristics Comparison

Feature	Subject Device: PISCES™-SA Standalone ALIF Interbody System	Primary Predicate: K191391-Globus HEDRON Lumbar Spacers	Comparison
Regulation	888.3080	888.3080	Equivalent
Product Code	OVD, MAX, PHM	MAX, OVD, PHM	Equivalent
Indications for Use	PISCES™-SA ALIF Spacers (Standalone Use, With Integrated Fixation) The PISCES™-SA (Standalone) ALIF Interbody System are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PISCES™-SA (Standalone) ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.	HEDRON™ Lumbar Spacers (HEDRON A™, HEDRON L™, HEDRON P™, HEDRON T™, and HEDRON RT™) are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. HEDRON™ Spacers	Equivalent

	• PISCES™-SA Used With Screws: When used with three (3) screws, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels. Hyperlordotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels. • PISCES™-SA Used With Anchors When used with three (3) anchors, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 levels. Hyperlordotic interbody devices (>20° lordosis) used with anchors, must always be used with supplemental fixation,	are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. HEDRON IA™ Integrated Lumbar Spacers are integrated lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). HEDRON IA™ Spacers are to be filled with autograft bone and/or	

	and may be used at 1 or 2 levels. <u>PISCES™ ALIF Spacers (Without Integrated Fixation)</u> PISCES™ ALIF Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PISCES™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared	allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with three screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). When used without screws or anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).	

	for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.		
Device Description	PISCES™-SA Standalone ALIF spacers are interbody fusion devices for the lumbar spine that may be used with three titanium alloy screws or anchors which accompany the implants. When used with screws and/or anchors, these devices are standalone interbody fusion devices. When used without screws and/or anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The PISCES™-SA spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The spacers are available in multiple sizes. The spacers 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 manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and must be sterilized prior to	HEDRON Integrated Lumbar Spacers are integrated anterior lumbar interbody fusion devices used to provide structural stability following discectomy. They are used with screws and/or anchors. All HEDRON Lumbar Spacers are additively manufactured from titanium powder per ASTM F3001. The mating screws and anchors are manufactured from titanium alloy, per ASTM F135 and F1295, and/or cobalt chrome alloy, per ASTM F1567. Titanium screws and anchors are available with or without hydroxyapatite (HA) coating, per ASTM F1185.	Equivalent

	use. The instruments used to insert the cage are manufactured from medical grade stainless steel and must be sterilized prior to use. The screws, anchors, blocking plates, and instruments are supplied in a re-usable tray for steam sterilization.		
Interbody Heights	9-19 mm in 2 mm increments	11-21 mm in 2 mm increments	Equivalent
Footprints	23x29 mm, 26x35 mm, 29x39 mm	24x30 mm, 26x34 mm, 29x39 mm	Equivalent
Lordotic Angles	8°, 16°, 20°, 24°	8°, 15°, 20°, 25°, 30°	Equivalent
Standalone Fixation Technology	Screws or Anchors	Screws or Anchors	Equivalent
Screw Diameters	Ø4.8 mm and Ø5.25 mm	Ø5.5 mm	Equivalent
Screw Lengths	15-52.5 mm in 2.5 mm increments	20-60 mm in 5 mm increments	Equivalent
Screw Types	Fixed, Variable, Self-tapping, Self-drilling	Fixed, Variable, Self-tapping, Self-drilling	Equivalent
Anchor Diameter	Ø4.8 mm	Ø5.5 mm	Equivalent
Anchor Lengths	22.5 mm, 25 mm, 27.5 mm	20 mm, 25 mm, 27 mm, 30 mm, 35 mm, 40 mm	Equivalent
Materials	Ti-6Al-4V ELI per ASTM F3001 and ASTM F136	Ti-6Al-4V ELI per ASTM F3001, Titanium alloy per ASTM F135 and F1295, and/or cobalt chrome alloy per ASTM F1537	Equivalent

Non-clinical Testing:

Substantial equivalence is supported by the results of mechanical testing including static and dynamic compression per ASTM F2077, static and dynamic compression shear per ASTM F2077, subsidence per ASTM F2267, expulsion testing, cantilever anchor bending, and anchor impaction testing. Substantial equivalence is also supported by performing cadaveric implantation and cadaveric Range of Motion (ROM) studies.

Conclusion:

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