



April 16, 2026

SpineCraft, LLC  
Ami Akallal-Asaad  
Vice President, Regulatory Affairs & QA  
777 Oakmont Lane  
Westmont, Illinois 60559

Re: K253260  
Trade/Device Name: ORIO-3D Cage System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: ODP, MAX, OVD  
Dated: September 26, 2025  
Received: March 19, 2026

Dear Ami Akallal-Asaad:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto: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

510(k) Number (if known)  
K253260

Device Name  
ORIO-3D Cage System

### Indications for Use (Describe)

The ORIO-3D Intervertebral Body Fusion Cervical Cages are indicated for spinal fusion procedures at one or two contiguous levels within the cervical spine in skeletally mature patients with cervical degenerative disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies, that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and imaging studies. The ORIO-3D Cervical Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone and with an FDA cleared cervical supplemental fixation system. The hyperlordotic implants ( $\geq 10^\circ$ ) are required to be used with an anterior cervical plate. Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the ORIO-3D Cervical Cages in the cervical spine.

The ORIO-3D Intervertebral Body Fusion Transforaminal Lumbar (TLIF or P-TLIF) Cages are indicated for intervertebral Body fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and imaging studies. Additionally, the ORIO-3D Intervertebral Body Fusion Transforaminal Lumbar Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis and sagittal deformity. The ORIO-3D Transforaminal Lumbar Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or cortico-cancellous bone. The ORIO-3D Transforaminal Lumbar Cages are intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbosacral spine. Patients must have undergone a regimen of at least six (6) months of nonoperative treatment prior to being treated with the ORIO-3D Transforaminal Lumbar Cages.

The ORIO-3D Intervertebral Body Fusion Anterior Lumbar (ALIF) Cages are indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Additionally, the ORIO-3D Intervertebral Body Fusion Anterior Lumbar Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis and sagittal deformity. When used with three titanium alloy ANTERIS bone screws, the ORIO-3D ALIF  $10^\circ - 20^\circ$  lordotic cages may be used as a standalone cage system in patients with DDD. Hyperlordotic ORIO-3D ALIF cages ( $>20^\circ$  lordosis) must be used with supplemental internal spinal fixation systems that are cleared for use in the lumbosacral spine. The ORIO-3D ALIF Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or cortico-cancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

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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## 510(k) Summary: **ORIO-3D Cage System**

Submitter	SpineCraft, LLC 777 Oakmont Lane Westmont, IL 60559 USA Tel: 1 630-920-7300. Fax: 1 630-920-7310	
Contact Person:	Ami Akallal-Asaad VP, Regulatory Affairs & QA SpineCraft, LLC <a href="mailto:a.asaad@spinecraft.com">a.asaad@spinecraft.com</a>	
Date Prepared:	October 21, 2025	
Trade Name:	<b>ORIO-3D Cage System</b>	
Common Name:	Intervertebral body fusion device	
Classification:	Class II	
Product Code and Classification Name:	<b>ODP:</b> Intervertebral body fusion device w/ Bone Graft - Cervical (21 CFR 888.3080) <b>MAX:</b> Intervertebral body fusion device w/ Bone Graft - Lumbar (21 CFR 888.3080) <b>OVD:</b> Intervertebral body fusion device w/ Integrated Fixation - Lumbar (21 CFR 888.3080)	
Predicate Devices ( <b>Primary Predicate is listed first</b> ):	Product Code	Predicate Trade Name / Predicate #
	ODP	Eminent Spine 3D Cervical Interbody Fusion System / K212701
	ODP	BAK/C Vista Interbody Fusion / P980048 S3
	ODP	HEDRON Cervical Spacers / K191243
	ODP	CONSTRUX Mini Ti Spacer System / K203342
	MAX	Eminent Spine 3D Lumbar Interbody Fusion Systems (Straight and Curved TLIF, PLIF) / K230219
	MAX	HEDRON™ Lumbar Spacer / K191391
	MAX	Lucent - Lumbar Intervertebral Body Fusion Device / K071724
	OVD	Eminent Spine Standalone ALIF Interbody Fusion System / K221936
	OVD	Modulus ALIF System / K230894
Device Description:	<p>The ORIO-3D Cage System devices are additively manufactured implants from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001 Class C. The system includes cervical intervertebral body fusion, straight transforaminal lumbar interbody fusion (TLIF), and anterior lumbar interbody fusion (ALIF) components. The ORIO-3D ALIF cages can be used with supplemental fixation, or when used with the ANTERIS bone screws, the ORIO-3D ALIF 10°- 20° lordotic cages may be used as a standalone system. The windows in the ORIO-3D Cage System devices are designed to accommodate bone graft material to support the development of spinal fusion. The teeth or roughened surfaces on the superior and inferior ends of the implants are intended to engage the adjacent vertebral bodies to provide resistance to expulsion</p>	

	<p>and help prevent migration. The implants are available in a variety of sizes and lordotic angles to accommodate the individual pathology and anatomical conditions of the patient.</p>
<p>Intended Use/Indication for Use:</p>	<p>The <b>ORIO-3D Intervertebral Body Fusion Cervical Cages</b> are indicated for spinal fusion procedures at one or two contiguous levels within the cervical spine in skeletally mature patients with cervical degenerative disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies, that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and imaging studies. The ORIO-3D Cervical Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone and with an FDA cleared cervical supplemental fixation system. The hyperlordotic implants (<math>\geq 10^\circ</math>) are required to be used with an anterior cervical plate. Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the ORIO-3D Cervical Cages in the cervical spine.</p> <p>The <b>ORIO-3D Intervertebral Body Fusion Transforaminal Lumbar (TLIF or P-TLIF) Cages</b> are indicated for intervertebral Body fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and imaging studies. Additionally, the ORIO-3D Intervertebral Body Fusion Transforaminal Lumbar Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis and sagittal deformity. The ORIO-3D Transforaminal Lumbar Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or cortico-cancellous bone. The ORIO-3D Transforaminal Lumbar Cages are intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbosacral spine. Patients must have undergone a regimen of at least six (6) months of nonoperative treatment prior to being treated with the ORIO-3D Transforaminal Lumbar Cages.</p> <p>The <b>ORIO-3D Intervertebral Body Fusion Anterior Lumbar (ALIF) Cages</b> are indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Additionally, the ORIO-3D Intervertebral Body Fusion Anterior Lumbar Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis and sagittal deformity. When used with three titanium alloy ANTERIS bone screws, the ORIO-3D ALIF <math>10^\circ - 20^\circ</math> lordotic cages may be used as a standalone cage system in patients with DDD. Hyperlordotic ORIO-3D ALIF cages (<math>&gt;20^\circ</math> lordosis) must be used with supplemental internal spinal fixation systems that are cleared for use in the lumbosacral spine. The ORIO-3D ALIF Cages are designed for use with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or cortico-cancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.</p>
<p>Technological Characteristics:</p>	<p>As established in this submission, the subject ORIO-3D Cage System is substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have substantially equivalent</p>

	<p>technological characteristics to the predicate devices through comparison of design, intended use, material composition, function, and range of sizes.</p>
<p>Performance Data:</p>	<p>The purpose of this submission is to introduce the ORIO-3D Cage System</p> <p>Mechanical performance testing was conducted to assess the safety and compatibility of the subject device. The following tests were performed:</p> <ul style="list-style-type: none"> <li>• Static axial compression (ASTM F2077-22)</li> <li>• Dynamic axial compression (ASTM F2077-22)</li> <li>• Static and dynamic shear-compression (ASTM F2077-22)</li> <li>• Dynamic shear-compression (ASTM F2077-22)</li> <li>• Static and dynamic Torsion (ASTM F2077-22)</li> <li>• Dynamic Torsion (ASTM F2077-22)</li> <li>• Subsidence (ASTM F2267-04 Reapproved 2018)</li> <li>• Expulsion (MED-SPN-EXP 2nd Edition, Rev. 0)</li> <li>• Particle Analysis (ASTM F1877-16)</li> </ul> <p>The results of these studies demonstrate that the subject ORIO-3D Cage System is substantially equivalent to legally marketed predicate devices.</p>
<p>Conclusion:</p>	<p>Based on the indications for use, technological characteristics, non-clinical performance testing, and comparison to predicate devices, the subject ORIO-3D Cage System has been shown to be substantially equivalent to legally marketed predicate devices.</p>