September 30, 2021

SpineCraft, LLC
Ami Akallal-Asaad
Vice President of Regulatory Affairs & Quality Assurance
777 Oakmont Lane, Suite 200
Westmont, Illinois 60559

Re: K211935
Trade/Device Name: ORIO-Ti Intervertebral Body Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: August 27, 2021
Received: September 2, 2021

Dear Ms. 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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211935

Device Name
ORIO-Ti Intervertebral Body Fusion Cage System

Indications for Use *(Describe)*
The ORIO-Ti cervical intervertebral body fusion cage 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. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. ORIO-Ti cervical intervertebral body fusion implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. ORIO-Ti cervical intervertebral body fusion implant is to be used with supplemental fixation that has been cleared for use in the cervical spine.

The ORIO-Ti lumbar intervertebral body fusion cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had at least six (6) months of non-operative treatment. ORIO-Ti lumbar intervertebral body fusion implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via a transforaminal, open posterior, anterior/anterolateral, or lateral approach. The ORIO-Ti lumbar intervertebral body fusion implants are to be used with supplemental fixation that have been cleared for use in the lumbosacral spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

SpineCraft
ORIO-Ti Intervertebral Body Fusion Cage System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the ORIO-Ti Cage System.

Date Prepared: August 27, 2021

1. 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.asaad@spinecraft.com

2. Trade name: ORIO-Ti Intervertebral Body Fusion Cage System

Common Name: Intervertebral body fusion device

Classification Name: Intervertebral body fusion device - Cervical per ODP 21 CFR 888.3080
Intervertebral body fusion device - Lumbar per MAX 21 CFR 888.3080
Class II

3. Predicate or legally marketed devices which are substantially equivalent:

Primary

- ORIO Intervertebral Body Fusion Cages (K090887) SpineCraft, LLC

Additional predicate devices

- BAK/C Vista Interbody Fusion (P980048) Zimmer
- Shoreline ACS Anterior Cervical Standalone (K170569) SeaSpine
- IVA Cage Ti (ACIF, PLIF, TLIF, DLIF, and ALIF) (K173080) Huvexel Co., Ltd
- Brigade Hyperlordotic ALIF Lumbar Cage (K123045) Nuvasive
- APEX-DL Spine System (K143683) SpineCraft, LLC
- ASTRA Spine System (K150417) SpineCraft, LLC

4. Description of the device:

The subject devices are intervertebral body fusion devices for use in cervical lumbar spinal surgery. They may also be referred to as interbody fusion devices or interbody cages. The devices are generally box-shaped or trapezoidal shaped with windows or pockets in their design to allow for the placement of autograft or allogenic bone graft. The ORIO-Ti Cage System is a Titanium alloy interbody fusion system comprised of various device configurations based on surgical approach and patient anatomy, and may be implanted via one of the following approaches: as a single device via an anterior cervical (ACDF), bi-laterally in pairs via a posterior (PLIF) approach; as a single device via a transforaminal (TLIF) approach; or as a single device via an anterior (ALIF) approach. The exterior of the devices has “teeth” on the superior and inferior surfaces to help prevent the devices from migrating once they are implanted.

Materials:
Titanium alloy Ti-6Al-4V ELI per ASTM F136.

5. Summary of Similarities and Differences in Technological Characteristics and Performance

ORIO-Ti Intervertebral Body Fusion Cage System is substantially equivalent to the ORIO cervical cage (K090887), the, the BAK/C Vista (P980048), the Shoreline ACS (K170569), the ORIO lumbar cages (K090887), IVA Cage Ti (ACIF, PLIF, TLIF, DLIF, and ALIF) (K173080) , the Brigade Hyperlordotic ALIF Lumbar Cage (K123045) in terms of intended use, design, materials used, mechanical safety and/or performances.

6. Indications for Use:

The ORIO-Ti cervical intervertebral body fusion cage 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. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. ORIO-Ti cervical intervertebral body fusion implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. ORIO-Ti cervical intervertebral body fusion implant is to be used with supplemental fixation that has been cleared for use in the cervical spine.

The ORIO-Ti lumbar intervertebral body fusion cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had at least six (6) months of non-operative treatment. ORIO-Ti lumbar intervertebral body fusion implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via a transforaminal, open posterior, anterior/anterolateral, or lateral approach. The ORIO-Ti lumbar intervertebral body fusion implants are to be used with supplemental fixation that have been cleared for use in the lumbosacral spine.

7. Non-clinical Test Summary:

The following tests were conducted:

- Static and dynamic axial compression (ASTM F2077-18)
- Static and dynamic shear-compression (ASTM F2077-18)
- Static and dynamic Torsion (ASTM F2077-18)
- Subsidence (ASTM F2267-04 Reapproved 2018)
- Expulsion (MED-SPN-EXP 2nd Edition, Rev. 0)

The results of this testing were compared to predicate systems, with the results being equal to or higher than the predicate systems.

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

Based on the supporting evidence provided, we believe that the subject ORIO-Ti Cage System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.