June 30, 2021

Spinal Elements, Inc.
Julie Lamothe, Ph.D., MBA
Vice President of Regulatory Affairs & Quality Assurance
3115 Melrose Dr., Suite 200
Carlsbad, California 92010

Re: K210044
Trade/Device Name: Crystal® Spinal System & Vertu® Spinal System, Lucent® Spinal System, Zeus® Spinal System, Ceres®-C Spinal System, Omega XP Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVE, ODP
Dated: April 15, 2021
Received: April 16, 2021

Dear Dr. Lamothe:

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 L. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Crystal® Spinal System

Indications for Use *(Describe)*

Crystal® devices are intended for spinal fusion at one or two contiguous levels in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Implants are to be implanted via an open, anterior approach for the C2-C3 disc space to the C7-T1 disc space and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with these devices.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Vertu® Spinal System

Indications for Use *(Describe)*

Vertu® devices are stand-alone interbody fusion devices intended for spinal fusion procedures at one level from the C2/C3 disc space to the C7/T1 disc space in skeletally mature patients with degenerative disc disease of the cervical spine. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Implants are to be implanted via an open, anterior approach and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

Device Name
Lucent® Spinal System

Indications for Use *(Describe)*

Lucent® are intervertebral body fusion devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Zeus® Spinal System

Indications for Use *(Describe)*

The Zeus® Lumbar Interbody Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. The Zeus® Lumbar Interbody Fusion Devices are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ceres®-C Spinal System

Indications for Use *(Describe)*

The Ceres®-C Stand-Alone Cervical 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 Ceres®-C Stand-Alone Cervical implant is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted with an anterior approach.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Omega XP Spinal System

Indications for Use *(Describe)*

The Omega XP device is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Omega XP device is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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)

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510(k) Summary
Interbody Fusion Device Spinal Systems

510(k) Number K210044

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-0121

Contact Information:
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Date Prepared: April 15, 2021

Device Identification

Proprietary Name	Crystal® Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	ODP

Proprietary Name	Vertu® Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	OVE

Proprietary Name	Lucent® Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	MAX

Proprietary Name	Zeus® Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	MAX

Proprietary Name	Ceres®-C Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	OVE

Proprietary Name	Omega XP Spinal Systems
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR Section 888.3080
Proposed Regulatory Class	Class II
Device Product Code	MAX

Device Description

The Spinal Elements' Crystal Cervical Interbody System is an intervertebral body fusion device for use in cervical spine surgery. The device is generally box-shaped with various holes throughout its geometry to allow for the placement of bone graft material. The exterior of the device has teeth or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned.

Spinal Elements' Vertu Cervical Interbody System is composed of an implant body and fixation screws. The implant body is generally a box-shaped device with holes through its body for the placement of graft material. Additionally, it has teeth located on its superior and inferior external surfaces to help keep the device from migrating once placed in its desired location. There are also screw holes located in the implant body. Each screw hole is lined in its internal surface with a titanium ring insert. Screws pass through screw holes of the implant body and affix to bone to help prevent implant migration. When fully seated, the screw head rests on the titanium insert of the screw hole.

The Lucent device is an interbody fusion device for use in lumbar spine surgery. Because PEEK is translucent, tantalum pins are placed in various locations of the PEEK device to serve as markers for radiographic visualization of the device orientation. The Lucent devices are of various shapes, heights, width, length and lordosis to suit patient anatomy.

The Zeus Interbody Fusion Devices are comprised of implants designed to treat the cervical and lumbar spine. The implants are available in a range of sizes and shapes to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

The Ceres-C Stand-Alone Cervical System includes a PEEK spacer with Tantalum markers, and a titanium interbody plate and screws. The spacer component is assembled to the interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes two holes for inserting one bone screw in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights.

The Omega XP System devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion in the lumbar spine. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various sizes and are designed to expand in height intra-operatively to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

Indications for Use

Crystal®:
Crystal® devices are intended for spinal fusion at one or two contiguous levels in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Implants are to be implanted via an open, anterior approach for the C2-C3 disc space to the C7-T1 disc space and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with these devices.

Vertu®:
Vertu® devices are stand-alone interbody fusion devices intended for spinal fusion procedures at one level from the C2/C3 disc space to the C7/T1 disc space in skeletally mature patients with degenerative disc disease of the cervical spine. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Implants are to be implanted via an open, anterior approach and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

Lucent®:
Lucent® intervertebral body fusion devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

Zeus®:
The Zeus® Lumbar Interbody Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. The Zeus® Lumbar Interbody Fusion Devices are intended be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Ceres ®-C:
The Ceres®-C Stand-Alone Cervical 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 Ceres®-C Stand-Alone Cervical implant is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted with an anterior approach.

Omega XP:
The Omega XP device is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc

confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Omega XP implants are to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Substantial Equivalence
The subject devices are substantially equivalent in indications for use, surgical technique, design features and instrumentation to the following predicate devices:

- Primary Predicate: Crystal® devices (K153352), Vertu® devices (K153352), Lucent® devices (K170235, K150061, K122967, K110632, K073348, K071724), Zeus® devices (K151310), Ceres®-C devices (K152972), and Omega XP (K150395)

Technological Characteristics
The subject device was established as substantially equivalent to another predicate device cleared by the FDA for commercial distribution in the Untied States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, operating principle and function.

Performance Data
No changes were made to the existing devices nor were any new components were added to the systems. Therefore, no additional testing was required or performed.

Conclusions
Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject devices have been shown to be substantially equivalent to the aforementioned predicate devices cleared by FDA for commercial distribution in the United States.