



August 1, 2016

Food and Drug Administration
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Silver Spring, MD 20993-0002

Spinal Elements, Incorporated
Julie Lamothe, Ph.D.
Regulatory Affairs & Quality Assurance Director
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K153352

Trade/Device Name: Vertu[®] & Vertu[®] Ti-Bond Cervical Interbody System,
Crystal[®] & Crystal[®] Ti-Bond Cervical Interbody System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: OVE, ODP

Dated: July 19, 2016

Received: July 20, 2016

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153352

Device Name

Vertu® & Vertu® Ti-Bond Cervical Interbody System

Indications for Use (Describe)

Vertu® & Vertu® Ti-Bond 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 (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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)

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:

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Food and Drug Administration
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PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)
K153352

Device Name
Crystal® & Crystal® Ti-Bond Cervical Interbody System

Indications for Use (Describe)

Crystal® & Crystal® Ti-Bond devices are intended for spinal fusion at one or two contiguous levels in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach from 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 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)

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*Spinal Elements, Inc.**Premarket Notification – Spinal Elements Vertu® & Vertu® Ti-Bond, Crystal® & Crystal® Ti-Bond Cervical Interbody Systems*

510(k) Summary
Vertu® & Vertu® Ti-Bond and Crystal® & Crystal® Ti-Bond Cervical Interbody Systems

510(k) Number _K153352_

Manufacturer Identification**Submitted by:**

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

Contact Information:

Julie Lamothe
Regulatory Affairs & Quality Assurance Director
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-1816
jlamothe@spinalelements.com

Date Prepared:

July 19, 2016

Proprietary Name :

Vertu® & Vertu® Ti-Bond and Crystal® & Crystal® Ti-Bond Cervical Interbody Systems

**Regulatory Identification/
Classification:**

Intervertebral body fusion device
Product Code: OVE – Vertu, ODP - Crystal
21 CFR 888.3080
Class II

Purpose of this 510(k)

This 510(k) seeks clearance for expanded indications to the Vertu® and Vertu® Ti-Bond Cervical Interbody System previously cleared for use under K122771 and K133218 and to the Crystal® and Crystal® Ti-Bond Cervical Interbody System previously cleared for use under K073351 and K133218.

Device Description

The Vertu and Vertu Ti-Bond Cervical Interbody System is composed of an implant body made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or polyetheretherketone (PEEK-Optima®) conforming to ASTM F2026 or PEEK-Optima® coated with commercially pure titanium per ASTM F1580 and fixation screws made from Ti-6Al-4V per ASTM F136 or ISO 5832-3 with a Nitinol clip conforming to ASTM

F2063. All implant bodies have a titanium insert lining the internal surface of the screw holes conforming to ASTM F136 or ISO 5832-3. The implant body is generally 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. 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 Crystal and Crystal Ti-Bond Cervical Interbody devices are generally a box-shaped device with various holes located throughout its geometry to allow for packing of bone graft material. The body of the implant is made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or polyetheretherketone (PEEK-Optima®) conforming to ASTM F2026 or PEEK-Optima® coated with commercially pure titanium per ASTM F1580. Superior and inferior surfaces of the device have teeth that help keep the device from migrating once placed in its desired location.

Indications for Use

Vertu

Vertu® & Vertu® Ti-Bond 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 (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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.

Crystal

Crystal® & Crystal® Ti-Bond devices are intended for spinal fusion at one or two contiguous levels in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach from 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 non-operative treatment prior to being treated with these devices.

Technological Characteristics

As was established in this submission, the subject device is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicates presented below through comparison in areas including indications for use, surgical technique, design features and instrumentation to the following predicate devices:

Primary Predicate

- Centinel Spine's STALIF C® and STALIF C-Ti™ (K150053)

Reference Devices

- Spinal Elements' Vertu® and Vertu® Ti-Bond Cervical Interbody System (K122771, K133218).
- Spinal Elements' Crystal® and Crystal® Ti-Bond Cervical Interbody System (K073351 and K133218).
- Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System - Cervical (K142264)
- ANATOMIC PEEK™ CERVICAL FUSION SYSTEM (K133653)

Performance Data

No changes were made to the existing Vertu, Vertu Ti-Bond, Crystal and Crystal Ti-Bond devices nor were any new components added to the system. Therefore, no additional testing was required or performed.

Conclusion

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject device has been shown to be substantially equivalent.