Spinal Elements Inc.
Julie Lamothe
Sr. Director Regulatory Affairs
3115 Melrose Dr., Suite 200
Carlsbad, California 92010

November 2, 2018

Re: K181837
Trade/Device Name: Spinal Elements Ti-Bond coated devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, MQP, ODP, OVE
Dated: August 3, 2018
Received: August 6, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181837

Device Name
Spinal Elements Ti-Bond coated devices

Indications for Use *(Describe)*

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 autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

Lucent

Lucent Magnum+ is an intervertebral body fusion device intended for spinal fusion procedure 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 autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

Crystal

Crystal 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.

Vertu

Vertu devices are stand-alone interbody fusion devices intended for spinal fusion procedures at one or two contiguous levels 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.

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510(k) Summary

Spinal Elements Ti-Bond coated devices

510(k) Number: K181837

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: October 30th 2018

Proprietary Name Spinal Elements Ti-Bond coated devices

Device Classification 21 CFR Section 888.3080
Proposed Regulatory Class Class II
Device Product Code MAX, OVD, MQP, ODP, OVE

Device Description

Spinal Elements' Ti-Bond® is an additive plasma sprayed coating of commercially pure titanium conforming to ASTM F1580. Spinal Elements' devices are coated with Ti-Bond®f on their surfaces. Spinal Elements Ti-Bond® coating presents a macro-, a micro and a nano-surface structure.

The indications for use of the devices coated with Ti-Bond® are not being modified from the ones cleared in their respective 510(k) and are as followed:

Indications for Use

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).
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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.

Vertu
Vertu devices are stand-alone interbody fusion devices intended for spinal fusion procedures at one or two contiguous levels 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.

Substantial Equivalence
The proposed characterization of the Ti-Bond® coating does not modify the devices previously cleared by Spinal Elements. Devices design, device specifications, material, manufacturing process, operating principle and indication for use are identical. Ti-Bond® coating is identical to the coating of the predicate devices coating:
Primary Predicate: Spinal Elements Lucent devices - K110632.
Additional Predicate: Spinal Elements Lucent devices – K150061
Additional Predicate: Spinal Elements Crystal/Vertu devices – K133218
Additional Predicate: Spinal Elements Lucent XP devices – K152011
Additional Predicate: Spinal Elements Lucent Lateral devices – K122967/K170235

Technological Characteristics
There are no changes to the predicate devices coating. All technical characteristics remain identical.

Performance Data
In support of this 510(k) Premarket Notification, Spinal Elements has conducted non-clinical testing demonstrating that the Spinal Elements Ti-Bond® coating present a surface topography at a macro, a micro and a nano scale.

Conclusion
Based on the indications for use, technological characteristics, and comparison to predicate device, the subject device with the Ti-Bond® coating has been shown to be substantially equivalent to the aforementioned predicate device cleared by FDA for commercial distribution in the United States.