DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 9, 2016

Spinal Elements, Incorporated
Julie Lamothe, Ph.D., M.B.A.
Regulatory Affairs and Quality Assurance Director
3115 Melrose Drive, Suite 200
Carlsbad, CA 92010

Re: K152011
Trade/Device Name: Lucent® Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 6, 2016
Received: May 9, 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 yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152011

Device Name
Lucent® Intervertebral Body Fusion Device

Indications for Use *(Describe)*
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.

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.

510(k) Summary
Lucent® XP and Lucent XP Ti-Bond®

510(k) Number __K152011__

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
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Date Prepared: July 17th, 2015

Proprietary Name	Lucent® Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Appliance, Fixation Spinal Intervertebral Body)
Proposed Regulatory Class	Class II
Device Product Code	MAX

Purpose of this 510(k)

This 510(k) seeks clearance for line additions to the Lucent, Lucent Ti-Bond and Lucent Lateral previously cleared for use under K071724 and K150061, K110632, K122967, respectively.

Device Description

The Lucent® XP device is an intervertebral body fusion device for use in lumbar spinal surgery. It may also be referred to as an interbody device or interbody cage. The Lucent® XP device is comprised of two PEEK endplates with teeth for engaging the vertebral body endplates on the outside of the device and an internal titanium mechanism for expanding the PEEK endplates of the device. The device is generally box-shaped with various holes throughout its design to allow for the placement of autograft. 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. The device is made from PEEK-Optima® grade LT1 conforming to ASTM F2026 with or without a coating of commercially pure titanium conforming to ASTM F1580. The internal mechanism is made from titanium alloy conforming to ASTM F136.

Indications for Use

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.

Substantial Equivalence

Lucent® XP and Lucent XP Ti-Bond® is identical in indications for use, manufacturing method, raw material and operating principles to the predicate devices cleared in:
K071724 – Primary Predicate
K093242 – Reference Device
K110632 – Additional Predicate
K122967 – Additional Predicate
K150061 – Additional Predicate
K123231 – Additional Predicate

Performance Data

Performance testing included:

- Static Compression Testing per ASTM F 2077-14
- Dynamic Compression Testing per ASTM F 2077-14
- Subsidence Testing per ASTM F 2267-11
- Static & Dynamic Compression Shear Testing per ASTM F2077-14

All data indicates that the device will perform as intended.
Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject device has been shown to be substantially equivalent to the aforementioned predicate devices cleared by FDA for commercial distribution in the United States.