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

November 29, 2017

Re: K170235
Trade/Device Name: Lucent®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 3, 2017
Received: November 6, 2017

Dear Julie 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 Part 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170235

Device Name
Lucent®

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 autograft or allogenic bone graft comprised of cancellous and/or corticancellous 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.

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510(k) Summary
Lucent®

510(k) Number: K170235

Manufacturer Identification
Submitted by: Spinal Elements, Inc.
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Date Prepared: November 20, 2016

Proprietary Name	Lucent®
Device Classification	21 CFR 888.3080 (Intervertebral Body Fusion Device)
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® previously cleared for use under K122967 and K150061, respectively.

Device Description
The Lucent® 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 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.

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 autograft or allogenic bone graft comprised of cancellous and/or corticancellous 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
The subject device is identical in indications for use, manufacturing method, raw material and operating principles to the predicate devices cleared in K122967 and K150061.

Technological Characteristics
The subject device has equivalent technological characteristics to its predicates presented below through comparison in areas including labeling/indications for use, general design features, function, material, manufacturing process and instrumentation:

- Spinal Elements Lucent Interbody Device K150061 - Primary
- Spinal Elements Lucent Interbody Device K122967 – Additional Predicate
- LANX, Inc. Lanx Lateral Device K103666 – Additional Predicate
- DePuy Spine, Inc. COUGAR® LS Lateral Cage Device K162327 – Additional Predicate

Performance Data
No clinical testing was found to be necessary. Given the type of changes made to the Lucent® device, no additional non-clinical testing was required or performed.

Materials and Standards
The previously cleared devices and the devices submitted herein may be manufactured from titanium (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3, polyetheretherketone (PEEK-Optima® provided by Invibio grade LT1) materials or polyetheretherketone (PEEK-Optima® provided by Invibio grade LT1) with a plasma sprayed coating of commercially pure titanium (per ASTM F 1580) on their superior and inferior surfaces. Because PEEK is radiolucent, tantalum (per ASTM F 560) pins are placed in various locations of the PEEK devices to serve as markers for radiographic visualization of device orientation.

Conclusion
Based on the indications for use, technological characteristics, 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.