December 10, 2018

Spinal Elements, Inc.
Ms. Cheryl Allen
Regulatory Affairs Manager
3115 Melrose Dr., Suite 200
Carlsbad, California 92010

Re: K182584
Trade/Device Name: Lucent® XP
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 20, 2018
Received: September 21, 2018

Dear Ms. Allen:

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)*
K182584

Device Name
Lucent® XP

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).

These devices are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Lucent® XP

510(k) Number K182584

I. SUBMITTER

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Date Prepared: October 29, 2018

II. DEVICE

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

III. Purpose of this 510k

This Traditional 510(k) seeks clearance for minor modifications to Lucent® XP intervertebral body fusion devices previously cleared under K152011 (10mm footprint), additional sizes (12mm footprint) and an expanded indication for all devices cleared under K152011 to include the use of allogenic bone graft comprised of cancellous and/ or corticancellous bone graft. The new devices have an identical intended use and fundamental scientific technology as the predicate.

IV. 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 or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. 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.

V. 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 autograph 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.

VI. SUBSTANTIAL EQUIVALENCE

The subject devices are substantially equivalent in indications for use, surgical technique, design features, manufacturing methods and raw materials to the following predicate devices:
Lucent® devices (K152011): Primary Predicate
Lucent® devices (K110632): Additional Predicate
Lucent® devices (K170235): Additional Predicate

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is identical in manufacturing method, raw material, basic operating principles and fundamental scientific technology to the predicate devices cleared in K152011. The subject devices include modifications to the existing 10mm footprint devices and additional sizes to the Lucent® XP devices. The subject device is seeking clearance for expanded indications for use to include autograph or allogenic bone graft comprised of cancellous and/or corticancellous bone graft. The subject device indications for use are identical to the indications for use as the additional predicate cleared in K170235. The devices will be marketed sterile and non-sterile. The specifications and manufacturing of the titanium coating is identical to that of the predicate devices cleared in K152011. The devices will be marketed with and without a plasma-sprayed porous titanium surface. The modifications do not raise any new issues of safety or effectiveness when compared to the predicate devices.

VIII. PERFORMANCE DATA

Biocompatibility Testing

The materials used to manufacture the subject devices as well as the manufacturing processes for the devices seeking clearance are identical as the materials and processes identified in previously cleared K152011 Lucent XP® submission.

Electrical safety and electromagnetic compatibility (EMC)
No electrical and electromagnetic compatibility testing were performed.

Software Verification and Validation Testing
The device does not contain software. Therefore, no software verification and validation testing were performed.

Mechanical testing
The subject device has the same performance characteristics as the previously cleared predicate device K152011. Non-clinical testing was used to support the decision of substantial equivalence. Non-clinical testing consisted of the following testing performed in accordance with the FDA guidance Class II Special Controls Guidance Document: Intervertebral Body Fusion Device:

- Static and Dynamic Compression Testing per ASTM F 2077-14
- Static and Dynamic Compression Shear Testing per ASTM F 2077-14

All data indicates that the device will perform as intended.

Animal Study
No animal studies were performed.

Clinical Studies
No clinical studies were performed.

VIIII. CONCLUSIONS

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.