March 26, 2021

Spinal Elements, Inc.
Julie Lamothe, Ph.D., MBA
Vice President of Regulatory Affairs
3115 Melrose Dr., Suite 200
Carlsbad, California 92010

Re: K203254
Trade/Device Name: Lucent® 3D Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 23, 2021
Received: February 25, 2021

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K203254

Device Name
Lucent® 3D

Indications for Use *(Describe)*

Lucent® 3D 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 corticocancellous 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® 3D

510(k) Number: K203254

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
P. 760-607-0121
F. 760-607-0125

Contact Information: Julie Lamothe
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-1816
jlamothe@spinalelements.com

Date Prepared: October 22, 2020

Proprietary Name	Lucent® 3D
Regulation 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

Device Description

The subject devices are intervertebral body fusion devices for use in lumbar spinal surgery. They may also be referred to as interbody fusion devices or interbody cages. The devices are generally box-shaped with various holes throughout their design to allow for the placement of autograft or allogenic bone graft. They include a lid which further facilitates installation of bone graft and which is shut prior to implantation. The exterior of the devices has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the devices from migrating once they are implanted.

The devices submitted herein are additively manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001.

Indication for Use

Lucent® 3D 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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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 (K150061): Primary Predicate
OmegaLIF devices (K150395): Additional Predicate

Technological Characteristics
The subject device was established as substantially equivalent to another predicate device cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, operating principle and function.

Performance Data
Performance testing included:

- Static Compression Testing per ASTM F 2077-18
- Static Compression Shear Testing per ASTM F 2077-18
- Dynamic Compression Testing per ASTM F 2077-18
- Dynamic Compression Shear Testing per ASTM F 2077-18
- Subsidence Testing per ASTM F 2267-18

All data indicates that the device will perform as intended.

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.