March 27, 2024

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

Re: K234150
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: February 29, 2024
Received: February 29, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Showalter -S

Brent 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234150

Device Name
Lucent® XP

Indications for Use *(Describe)*
Lucent® XP 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.

510(k) Summary
Lucent® XP

DATE: February 28, 2024

I. SUBMITTER

Company Information: Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010

Contact Information: Dr. Julie Lamothe
Vice President Of Regulatory Affairs and Quality
760-607-1816
jlamothe@spinalelements.com

II. DEVICE

Proprietary Name	Lucent® XP
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080
Proposed Regulatory Class	Class II
Device Product Code	MAX

III. DEVICE DESCRIPTION

Lucent® XP intervertebral body fusion 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.

IV. INDICATION FOR USE

Lucent® XP 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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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.

VII. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

Lucent® XP intervertebral body fusion devices are identical or similar to cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (design, components, material, chemical composition, and principle of operation, manufacturing, labeling, sterility, etc) and non-clinical performance (i.e. mechanical testing).

VIII. PERFORMANCE DATA

Mechanical testing

The subject device has the same performance characteristics as the previously cleared predicate devices. 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 and per ASTM F 2077-14
- Static and Dynamic Compression-Shear Testing and per ASTM F 2077-14

Testing conducted demonstrates substantial equivalence to the predicate devices.

VI. SUBSTANTIAL EQUIVALENCE

Lucent® XP intervertebral body fusion devices have been found to be substantially equivalent to the predicate devices with respect to intended use/indications for use, device description, technological characteristics, and performance. The information provided in this premarket submission supports substantial equivalence to the predicate devices listed below.

- Primary Predicate: Lucent® XP intervertebral body fusion System - K182584
- Additional Predicate: Lucent® XP intervertebral body fusion System - K202298
- Additional Predicate: Lucent® intervertebral body fusion System – K071724
- Additional Predicate: Opticage Interbody Fusion System – K113527