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

July 22, 2015

Custom Spine, Incorporated
Mr. Mahmoud Abdelgany
Chief Executive Officer
9 Campus Drive
Parsippany, New Jersey 07054

Re: K143143
Trade/Device Name: PATHWAY ELIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2015
Received: June 18, 2015

Dear Mr. Abdelgany:

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.

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)*
K143143

Device Name
PATHWAY ELIF

Indications for Use *(Describe)*

The PATHWAY ELIF device(s) is intended for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative Disc Diseases (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

The PATHWAY ELIF device is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems. The device(s) is intended to be used with autogenous bone graft.

Patients must have undergone a regiment of at least (6) months of non-operative treatment prior to being treated with the PATHWAY ELIF device(s).

The PATHWAY ELIF device can be used in one of two methods:

Transforaminal Lumbar Interbody Fusion (TLIF)
Used as a TLIF, a single device is implanted in the appropriate location to provide support for a transforaminal approached surgery.

Posterior Lumbar Interbody Fusion (PLIF)
Used as a PLIF, two devices are implanted in the appropriate locations to provide support to the spine for a posterior surgery.

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.

Section VIII. 510(K) SUMMARY

Name of Firm

Custom Spine, Incorporated
9 Campus Dr.
Parsippany, NJ 07054
Phone: (973) 808-0019
Fax: (877) 770-7746

Date Prepared

July 17, 2015

Official Correspondent

Mahmoud Abdelgany
Chief Executive Officer
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Phone: (973) 808-0019
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E-mail: mahmoud@customspine.com

Establishment Number

3005129649

Device Name

Legally Marketed Trade Name: PATHWAY ELIF
Common Name: INTERVERTEBRAL BODY FUSION DEVICE
Device Classification: Class II
Regulation Number: 21 CFR 888.3080
Device Product Codes: MAX

Predicate Devices

Custom Spine PATHWAY (K111774)

Device Description

The PATHWAY ELIF implant features three prescribed lordotic angle / height positions and is available in two lengths for posterior lumbar fusion. It allows lordotic adaptability and height restoration to meet patient anatomy. It is comprised of upper and lower expandable surfaces preassembled with a posterior height maintenance component. The device can be expanded to fixed configurations of 0°, 8°, and 16° positions. Each position after 0° provides approximately 2mm of additional mid-body height increase. The superior and inferior surfaces of all components are coated with plasma sprayed titanium to provide a roughened finish.

Indications for Use

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Used as a TLIF, a single device is implanted in the appropriate location to provide support for a transforaminal approached surgery.

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Used as a PLIF, two devices are implanted in the appropriate locations to provide support to the spine for a posterior surgery.

Materials

Materials used in the PATHWAY ELIF device(s) are:

- Titanium alloy: Ti-6Al-4V ELI according to ISO 5832-3 and ASTM F136, and are coated with plasma spray titanium.

Performance Data

Testing was performed in accordance with the following standard(s):

- ASTM F2077-11, “Test Methods for Intervertebral Body Fusion Devices”
- ASTM F2267-04(2011), “Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression”
- ASTM F04.25.02.02, Draft standard for implant expulsion
- ASTM F1580-07 , Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants
- ASTM F1854-09, Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM F1044-05, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147-05, Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1160-05, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic
- ASTM F1978-00, Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the TaberTM Abraser

Non-Clinical Testing

The PATHWAY ELIF System demonstrated equivalent performance to the predicate through static and dynamic axial compression shear testing per ASTM F2077, subsidence testing per ASTM F2267, and expulsion testing per ASTM Draft F04.25.02.02. In addition, a cadaver study was conducted to demonstrate usability and functionality.

Technological Characteristics

The PATHWAY ELIF System consists of a series of Titanium alloy: Ti-6Al-4V ELI according to ISO 5832-3 and ASTM F136, and are coated with plasma spray titanium. The proposed devices are the same as the current predicate devices already on the market with minor differences in shapes and sizes.

Test data has shown that the proposed devices are equivalent to the predicate devices and the minor differences will not impact the devices safety and effectiveness.

Substantial Equivalence Statement

Documentation is provided to demonstrate that the PATHWAY ELIF System is substantially equivalent to its predicate devices in terms of its material, design, indications for use, and performance characteristics.