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

May 16, 2017

LDR Spine USA, Inc.
Bradley W. Strasser, RAC
Project Manager, Regulatory Affairs
13785 Research Blvd, Suite 200
Austin, Texas 78750

Re: K162133
Trade/Device Name: VerteFIT™ Corpectomy Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 14, 2017
Received: April 17, 2017

Dear Mr. Strasser:

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" (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.

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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162133

Device Name
VerteFIT™ Corpectomy Cage System

Indications for Use *(Describe)*

The VerteFIT™ Corpectomy Cage System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 to L5) to replace collapsed, damaged or unstable vertebral bodies due to tumor or trauma (i.e., fracture). The VerteFIT Corpectomy Cage System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The VerteFIT Corpectomy Cage System device may be used with allograft or autograft. The VerteFIT implants are intended to be used with supplemental spinal fixation systems that have been cleared by FDA for use in the thoracic and/or lumbar spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Owner's Name & Address:

LDR Spine USA
13785 Research Blvd. Suite 200
Austin, TX 78750

Contact Person:

Bradley W. Strasser, RAC
Project Manager, Regulatory Affairs
Phone: (512) 344-3355
Fax: (512) 795-8306
Email: brad.strasser@zimmerbiomet.com

Date:

February 15, 2017

Trade Name:

VerteFIT™ Corpectomy Cage System

Common Name:

Spinal Vertebral Body Replacement Device

Panel:

Orthopedic

Product Code:

MQP

Classification:

Class II (21 CFR 888.3060)

Predicate Devices:

Primary Predicate:
K2M Santorini Corpectomy Cage System (K111294, January 27, 2012)
Secondary Predicate:
Globus Medical FORTIFYTM I-R (K121107, July 3, 2012)
Reference Predicate:
LDR Spine ROI-C Titanium (K151934, December 7, 2015)

Device Description

VerteFIT Corpectomy Cages are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The components include central PEEK cores and titanium-coated PEEK endcaps which are available in a range of sizes and options to accommodate the anatomical needs of a wide variety of patients. The core and endcaps can be intraoperatively assembled to best fit patient anatomy requirements. Each endcap has a central axial chamber to allow autogenous bone graft or allograft to be packed inside of the spacer. Unidirectional teeth on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. VerteFIT endcaps (superior and inferior) have slots to accommodate VerteBRIDGE anchoring plates.

Indications for Use:

The VerteFIT™ Corpectomy Cage System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 to L5) to replace collapsed, damaged or unstable vertebral bodies due to tumor or trauma (i.e., fracture). The VerteFIT Corpectomy Cage System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The VerteFIT Corpectomy Cage System device may be used with allograft or autograft. The VerteFIT implants are intended to be used with supplemental spinal fixation systems that have been cleared by FDA for use in the thoracic and/or lumbar spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Non-Clinical Performance Data:

Mechanical testing was conducted in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s., May 3, 2004" to demonstrate substantial equivalence to the predicate system(s). The following testing was done:

- Static & dynamic compression (ASTM F2077)
- Static & dynamic shear compression (ASTM F2077)
- Static & dynamic torsion (ASTM F2077)
- Subsidence (ASTM F2267)
- Cage and anchor expulsion (F-04.25.05.02)
- Corrosion testing (ASTM F2129)

Clinical Performance Data:

Clinical testing was not required to demonstrate substantial equivalence.

Basis of Substantial Equivalence:

The VerteFIT Corpectomy Cage System implants are similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).