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

August 4, 2016

LDR Spine USA, Incorporated
Mr. James E. Wilson
Regulatory Affairs Specialist
13785 Research Boulevard, Suite 200
Austin, Texas 78750

Re: K161798
Trade/Device Name: FacetBRIDGE® System
Regulatory Class: Unclassified
Product Code: MRW
Dated: July 28, 2016
Received: July 29, 2016

Dear Mr. Wilson:

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 Parts 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,

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)*
K161798

Device Name
FacetBRIDGE® System

Indications for Use *(Describe)*
The FacetBRIDGE® System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1. For transfacet fixation the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. This system is intended for use only with bone graft material. This system is not to be used with bone cement. The FacetBRIDGE® System is indicated for treatment for any or all of the following:
• Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity,
• Spondylolisthesis,
• Spondylolysis,
• Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies,
• Degeneration of the facets with instability,
• Trauma including spinal fractures and/or dislocations.

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."

a passion for innovation

510(k) Summary

Owner's Name & Address:

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

Contact Person:

Mr. Jamie E. Wilson
Regulatory Affairs Specialist
Phone: (512) 344-3355
Fax: (512) 795-8306
Email: jamie.wilson@ldrspine.com

Date: July 28, 2016

Trade Name: FacetBRIDGE® System

Common Name: System, Facet Screw Spinal Device

Panel: Orthopedic

Product Code: MRW

Classification: Unclassified

Predicate Devices:

Primary Predicate:
FacetBRIDGE® System – Facet Screws (K152137, LDR Spine 1/25/2016)

Device Description:

The FacetBRIDGE® System is a set of screws used for translaminar or transfacet fixation in the spine as an adjunct to fusion.

Each FacetBRIDGE® System construct consists of a screw and optional polyaxial washer both manufactured from Ti-6Al-4V ELI. The screw is cannulated to aid in placement via a guide wire. This system is not to be used with bone cement. The safety and effectiveness of using bone cement with this system has not been established.

Indications for Use:

The LDR FacetBRIDGE® System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1. For transfacet fixation the screws are inserted posteriorly

through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. This system is intended for use only with bone graft material. This system is not to be used with bone cement. The LDR FacetBRIDGE® System is indicated for treatment for any or all of the following:

- Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity,
- Spondylolisthesis,
- Spondylolysis,
- Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies,
- Degeneration of the facets with instability,
- Trauma including spinal fractures and/or dislocations.

Purpose of this submission:

The purpose of this submission is to introduce a line extension which includes an additional washer design for the FacetBRIDGE® System.

Non-Clinical Performance Data:

Non-clinical performance bench testing conducted to support substantial equivalence for the FacetBRIDGE® System included:

- Engineering and dimensional analysis
- Functional verification study utilizing sawbones.
- Endotoxin Testing

The results of detailed engineering analyses and functional verifications ensure that the addition of a new washer does not create a new worst case in terms of functionality or mechanical strength and therefore this line extension is substantially equivalent to the predicate system and does not require new testing.

Clinical Performance Data:

Clinical testing was not required to demonstrate substantial equivalence.

Basis of Substantial Equivalence:

The FacetBRIDGE® System is substantially equivalent to the predicate devices based on intended use and indications for use. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness and the scientific data from assessments of these characteristics demonstrate that the subject device is fit for its intended use and comparable to the predicate device. Therefore, the modified FacetBRIDGE® System is overall is substantially equivalent to the predicate FacetBRIDGE® System.