



Food and Drug Administration
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Silver Spring, MD 20993-0002

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

January 25, 2016

Re: K152137
Trade/Device Name: FacetBRIDGE® System
Regulatory Class: Unclassified
Product Code: MRW
Dated: January 4, 2016
Received: January 5, 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" (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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152137

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.

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510(k) Summary

Owner's Name & Address: LDR Spine USA
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: January 19, 2016

Trade Name: FacetBRIDGE® System

Common Name: System, Facet Screw Spinal Device

Panel: Orthopedic

Product Code: MRW

Classification: Unclassified

Predicate Devices: **Primary Predicate:**
TranS1 Facet Screw- (K073515)
Additional Predicates:
Apollo Spine Venus Facet Screw System – (K120340)
X-Spine Zyfix - (K123932)

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 construct consists of a screw and 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 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.

Purpose of this submission:

The purpose of this submission is to introduce the FacetBRIDGE System of facet screws into the market.

Non-Clinical Performance Data:

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

- Static Three-point Bend per ASTM F1264-14
- Dynamic Three-point Bend Fatigue per ASTM F1264-14
- Axial Pullout Strength per ASTM F543e1
- Torque to Failure per ASTM F543e1
- Screw/washer pull-through testing

The results of this non-clinical testing demonstrate the device is substantially equivalent to legally marketed predicate devices.

Technological Characteristics

The FacetBRIDGE System has similar technological characteristics when compared to the predicate devices. The system is comprised of similar components including screws and washers manufactured from titanium alloy provided in various sizes. The FacetBRIDGE System, like the predicates, is indicated for use at C2 through S1 as an adjunct to fusion. The FacetBRIDGE system also achieves stabilization of the spine by immobilizing the facet joints in a method similar to the predicate devices.

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 scientific data from assessment of technological characteristics of this device demonstrate that the subject device is comparable to predicate devices. Therefore, the FacetBRIDGE System is substantially equivalent to the predicate devices.