

510(K) SUMMARY

Submitter's Name:	LDR Spine USA, Inc.
Submitter's Address:	13785 Research Boulevard, Suite 200 Austin, TX 78750
Submitter's Telephone:	512.344.3333
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	31 October 2013
Trade or Proprietary Name:	InterBRIDGE Interspinous Posterior Fixation System
Common or Usual Name:	Appliance, Fixation, Spinal Interlaminar Spinous Process Plate
Classification:	Class II per 21 CFR §888.3050
Product Code:	PEK
Classification Panel:	Division of Orthopedic Devices - Posterior Spine Device Branch
Predicate Devices:	OsteoMed Spine PrimaLOK™ Interspinous Fusion System (K100354) NuVasive Affix Spinous Process Plate (K073278, K131238) Southern Spine StabiLink™ MIS Spinal Fixation System (K123093)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The InterBRIDGE® System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion.

The system is implanted via a posterior approach to the spine. The InterBRIDGE® System includes various sizes of titanium plate constructs. The implants are provided sterile and single use. The instrumentation is non-sterile and reusable.

INDICATIONS FOR USE

The InterBRIDGE® System is a posterior, non-pedicle supplemental fixation device intended for single-level use only in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (fracture or dislocation)
- Tumor

The InterBRIDGE® system is not intended for stand-alone use.

TECHNICAL CHARACTERISTICS

Data was provided which demonstrated the InterBridge® System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function. The devices are manufactured from titanium alloy (ASTM F136). The predicate devices are manufactured from the same or similar materials.

PERFORMANCE DATA

The InterBRIDGE has been tested in the following test modes:

- Static axial compression bending per modified ASTM F1717-12a
- Static torsion per modified ASTM F1717-12a
- Dynamic axial compression bending fatigue per modified ASTM F1717-12a
- Static axial pull-out resistance
- Static plate dissociation

The results of this non-clinical testing show that the strength of the InterBRIDGE is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics, indications for use, and mechanical performance data lead to the conclusion that the InterBRIDGE is substantially equivalent to the predicate device.



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

March 7, 2014

LDR Spine, USA, Incorporated
% Ms. Meredith May
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, CO 80918

Re: K133363

Trade/Device Name: InterBRIDGE Interspinous Posterior Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: January 29, 2014
Received: November 5, 2014

Dear Ms. May:

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.

Page 2 – Ms. Meredith May

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Vincent ~~F~~Devlin -S

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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: InterBRIDGE Interspinous Posterior Fixation System

510(k) Number: K133363

The InterBRIDGE® System is a posterior, non-pedicle supplemental fixation device intended for single-level use only in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (fracture or dislocation)
- Tumor

The InterBRIDGE® system is not intended for stand-alone use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133363