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

October 29, 2014

Zimmer Spine, Incorporated
Ms. Holly Seppanen
Regulatory Affairs Project Manager
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K142053
Trade/Device Name: Universal Clamp Spinal Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: August 7, 2014
Received: August 8, 2014

Dear Ms. Seppanen:

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 yours,

Ronald P. Jean -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)*

K142053

Device Name
Universal Clamp Spinal Fixation System

Indications for Use *(Describe)*

The Universal Clamp Spinal Fixation System is a temporary implant for use in orthopedic surgery.
The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.
The Universal Clamp System may also be used in conjunction with other medical grade implants made of similar metals whenever "wiring" may help secure the attachment of the other implants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 ***Universal Clamp*® Spinal Fixation System**

Date of Summary Preparation:	October 21, 2014
Company:	Zimmer Spine, Inc. Cité Mondiale 23, Parvis des Chartrons 33080 Bordeaux, France
Establishment Registration Number:	3003853072
Company Contact:	Holly Seppanen Regulatory Affairs Project Manager Email: Holly.Seppanen@zimmer.com Office: 952.830.6240
Trade Name(s):	*Universal Clamp Spinal Fixation System*
Device Name (Common Name):	Spinal Fixation System
Device Classification:	Class II
Regulation Number and Product Code(s):	21 CFR § 888.3010 / OWI
Regulation Name:	Bone fixation cerclage
Predicate(s):	Zimmer Spine *Universal Clamp Spinal Fixation System* (K110348*, K091190, K081622, K060009) Spinal Concepts CFIX Cable System (K974020) ***primary predicate**

General Device Description:

The *Universal Clamp Spinal Fixation System* consists of a woven band with a stiff guiding section at one end and metal buckles at the other end, implantable grade metal clamps that mate with 4.5mm – 6.35mm diameter rods, and an implantable grade metal locking screw that tightens the clamp over the band securing it to the connecting rod.

Implants made from implantable grade titanium, implantable grade titanium alloy, and implantable grade cobalt chromium may be used together. Due to the risk of galvanic corrosion, never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. All implants are provided sterile and are single use only; the implants should not be re-used or re-sterilized under any circumstances.

Zimmer Spine - 510(k) – *Universal Clamp System* – 510(k) Summary

Indications for Use:

The *Universal Clamp Spinal Fixation System* is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;

2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis;

3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The *Universal Clamp System* may also be used in conjunction with other medical grade implants made of similar metals whenever "wiring" may help secure the attachment of the other implants.

Summary of Performance Testing:

Performance testing (static axial pushdown, static axial rotation, static axial tension, and dynamic tension) was conducted to in accordance with ASTM F1798. All performance testing passed the acceptance criteria and demonstrated the device performed as well or better than the predicate systems.

Substantial Equivalence:

The subject Zimmer Spine *Universal Clamp Spinal Fixation System* configurations are similar to predicate devices with respect to intended use, mechanical and functional performance and technological characteristics. The information contained in this submission show that the subject *Universal Clamp Spinal Fixation System* is substantially equivalent to the predicate devices.