MAY 2 1 2014

zimmer spine	**510(k) SUMMARY** *Trinica*® Anterior Lumbar Plate System

Date of Summary Preparation:	March 07, 2014
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact (Primary):	Donna M. Semlak Senior Regulatory Affairs Specialist Email: Donna.Semlak@zimmer.com Office: 952.857.5643 Email Fax: 952.857.5843
Trade Name(s):	*Trinica*® Anterior Lumbar Plate System
Device Name (Common Name):	Spinal Intervertebral Body Fixation Orthosis
Device Classification:	Class II
Regulation Number and Product Code(s):	21 CFR § 888.3060 / KWQ
Predicate Devices:	*Trinica*® Anterior Lumbar Plate System (K061353)

General Device Description:

The *Trinica*® Anterior Lumbar Plate (ALP) System is a temporary supplemental fixation device consisting of a variety of shapes and sizes of plates and screws. The *Trinica* Anterior Lumbar Plate System is used as an implant for the correction and stabilization of the spine. This system provides temporary stabilization and augments the development of a solid spinal fusion. Additionally, this system provides the surgeon with the ability to supplement an interbody device with anterior plate fixation. The *Trinica* Anterior Lumbar Plate System components can be locked into a variety of configurations and each construct may be customized to individual cases. The plates are low profile and anatomically designed to provide optimal fit from either anterior or anterior-lateral approach. This system also features anti-migration locking caps to help secure the fixation screws. All *Trinica* Anterior Lumbar Plate System implant components are made from titanium alloy (Ti-6Al-4V ELI).

The Trinica® Anterior Lumbar Plate System is supplied with the instrumentation necessary for implantation of the system. The *Trinica*® Anterior Lumbar Plate System is for single use only.

Indications for Use:

The *Trinica*® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. This system is indicated in the treatment of lumbar or lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous fusion.

Summary of Technological Characteristics

The technological characteristics remain the same for the subject *Trinica*® Anterior Lumbar Plate System as the currently marketed (predicate) *Trinica*® Anterior Lumbar Plate System, which received FDA clearance K061353. There are no changes to the implants (plates and/or screws) and instrumentation within this submission. This submission is only addressing a sterilization tray bracket modification.

All the technology characteristics remain the same: same system's intended use, same mechanical and functional scientific technology; same materials and the same substantially equivalent performance characteristics.

The *Trinica*® Anterior Lumbar Plate System provides temporary supplemental fixation devices consisting of a variety of shapes and sizes of plates and screws; intended to provide anterior lumbar temporary stabilization and the development of a solid spinal fusion per the indications for use, as stated in the Section above.

Trinica® Anterior Lumbar Plate System includes: plates, bone screws with locking caps, and instrumentation necessary to implant this specific system. The *Trinica*® Anterior Lumbar Plate System is for single use only.

Summary of Performance Testing

Sterilization testing of the components/instruments contained in the subject Trinica ALPS tray were assessed and tested appropriately to design controls; i.e. sterilization validation. The test results demonstrated the modified device met the requirements of ISO 17665 and AAMI TIR12.

Substantial Equivalence

Zimmer Spine considers the subject Trinica Anterior Lumbar Plate System to be substantially equivalent to the currently marketed Trinica Anterior Lumbar Plate System, K061353, as there are no changes to: the intended use, mechanical and functional performance, functional scientific technology, the implants (plates or screw) and/or instrumentation.

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 21, 2014

Zimmer Spine, Incorporated
Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K140611
Trade/Device Name: Trinica® Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 7, 2014
Received: March 10, 2014

Dear Ms. Semlak:

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)*
K140611

Device Name
Trinica® Anterior Lumbar Plate System

Indications for Use *(Describe)*
The Trinica® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. This system is indicated in the treatment of lumbar or lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous fusion.

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)*

Ronald P. Jean -S
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