K061353
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AUG 3 0 2006

zimmer
spine

510(k) Summary

Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439
Company Contact:	Tim Crabtree Senior Regulatory Affairs Specialist
Date Prepared:	May 12, 2006
Device Name:	Trinica® Anterior Lumbar Plate System
Common Name:	Spinal Fixation System
Classification Name:	Spinal intervertebral body fixation orthosis
Classification:	21 CFR §888.3060
Product Code:	KWQ
Predicate Devices:	Synthes Anterior Tension Band (ATB) System DePuy Spine AEGIS Anterior Lumbar Plate System

Description of Device: The *Trinica* Anterior Lumbar Plate 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).

Intended 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.

Comparison of Technological Characteristics: The Zimmer Spine *Trinica* Anterior Lumbar Plate System shares the same technological characteristics as the Synthes Anterior Tension Band (ATB) System and the Depuy Spine's AEGIS Anterior Lumbar Plate System. These characteristic include materials, range of sizes, and intended use.

Substantial Equivalence: The Zimmer Spine *Trinica* Anterior Lumbar Plate System is substantially equivalent to the Synthes Anterior Tension (ATB) System and the Depuy Spine's AEGIS Anterior Lumbar Plate System in design, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2006

Zimmer Spine, Inc.
% Mr. Tim Crabtree
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K061353
Trade 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: August 22, 2006
Received: August 25, 2006

Dear Mr. Crabtree:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061353

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Trinica® Anterior Lumbar Plate System

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.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061353