MAY 2 9 2012

510(k) Summary

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Judith Rosen Senior Regulatory Affairs Specialist Telephone: (973) 576-0032 ext. 28138 Fax: (973) 884-8792 Email: judith.rosen@zimmer.com
Date:	May 25, 2012
Trade Name:	TM Ardis® Interbody System
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device, Lumbar 21 CFR § 888.3080,

Device Panel/Product Code: Orthopedic / MAX

Device Description:
The TM Ardis® Interbody System implant is a convex, straight TLIF or PLIF device for interbody fusion of the anterior column of the spine. TM Ardis is designed for fusing the adjacent bony surfaces and may be used to replace a disc at one or two contiguous levels in L2-S1. The superior and inferior surfaces of the device are textured to provide increased stability and convex to conform to the vertebral endplates. The device also has two slots on the posterior end to mate with the insertion instrument. The TM Ardis device is wholly comprised of Trabecular Metal Porous Tantalum. Surgical instrumentation for use with the proposed system will be fabricated from surgical grade stainless steel and other applicable materials.

Indications for Use:
The TM Ardis® Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The TM Ardis® Interbody System device is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Device Technological Characteristics and Comparison to Predicate Device(s):
The TM Ardis® Interbody System was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include the Ardis® Interbody System by Zimmer Spine

(K073202), Lucent® Lumbar Interbody System by Spinal Elements (K071724), TM-S Fusion Device by Zimmer Trabecular Metal Technology (K103033).

The TM Ardis® Interbody System has the identical material as previously cleared TM-S predicate devices. The intended use and indications for use of the subject device are similar to those of its predicate devices. The sizes, design features and overall geometry of the device in the current submission are similar to the cleared predicate devices.

There are no significant differences between the TM Ardis® Interbody System and the predicate devices currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy. The subject system is similar to its predicate devices with respect to intended use/indications for use, material, technological characteristics and basic principles of operation.

Performance Data:
Mechanical testing was performed on the TM Ardis® Interbody System in accordance with ASTM F2077-03: Test Methods for Intervertebral Body Fusion Devices, ASTM F2267-04: Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression, Guidance for Industry and FDA Staff; Spinal Systems 510(k)s; May 3, 2004 and Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007 and was comprised of the following tests; Axial Compression – Static and Dynamic, Compression Shear – Static and Dynamic, Subsidence, Torsion – Static and Dynamic and Expulsion. The results of testing and analyses conducted demonstrate that the proposed system adequately meets the predetermined requirements established for its mechanical performance.

Substantial Equivalence:
The TM Ardis® Interbody System is substantially equivalent to its predicate devices with respect to intended use/indications for use, materials, technological characteristics and basic principles of operation as demonstrated by the supporting performance testing data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Trabecular Metal Technology, Incorporated
% Ms. Judith Rosen
Senior Regulatory Affairs Specialist
10 Pomeroy Road
Parsippany, New Jersey 07054

MAY 2 9 2012

Re: K113561
Trade/Device Name: TM Ardis® Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 03, 2012
Received: May 04, 2012

Dear Ms. Rosen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

For

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

Enclosure

Indications for Use

510(k) Number (if known): K113561

Device Name: TM Ardis® Interbody System (TM TPLIF)

Indications for Use:

The TM Ardis® Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The TM Ardis® Interbody System device is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113561