zimmer spine	**510(k) SUMMARY** ***Ardis® Interbody System***

JAN 30 2014

Date of Summary Preparation: October 08, 2013

Submitter:
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Establishment Registration Number: 2184052 (Minneapolis)

Company Contact:
Michelle Lenz
Regulatory Affairs Specialist
Email: Michelle.Lenz@Zimmer.com
Office 952.830.6243
Fax 952.837.6843

Secondary Contact:
Jonathan Gilbert
Regulatory Affairs Director
Email: Jonathan.Gilbert@Zimmer.com
Office: 952.830.6385
Fax: 952.837.6985

Trade Name: Ardis® Interbody System

Device Name (Common Name): Interbody Fusion Device

Device Classification: Class II

Product Code(s): MAX

Regulation Number: 21 CFR § 888.3080

Regulation Description: Intervertebral Body Fusion Device

Predicate Device: Ardis Spacer (K073202)

General Device Description:

The Ardis® Interbody System is an implant device for interbody fusion of the anterior column of the spine. It is available in various height, width and length options. The device has a textured "tooth" pattern on both the cranial and caudal sides of the device and teardrop holes on the medial and lateral sides of the device. The implant incorporates an internal cavity that allows for the placement of bone graft material.

The system includes the single-use spacer implant, as well as the associated reusable instruments used for site preparation, trialing, and placement/extraction of the device, such as rasps, tamps, shavers, bone funnel, bone tamp, slap-hammer, T-handle and trials.

Indications for Use:

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

Summary of Technological Characteristics:

Implant Design: The Ardis Interbody System implant is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths and heights.

Implant Placement: Ardis Interbody System implants are designed to be placed through a posterior or transforaminal approach and to address vertebrae in the lumbosacral region of the spine. The system contains implants of various sizes to accommodate different patient anatomy, and instruments for site preparation, trialing, and placement/extraction.

Materials, Implants and Instruments: Ardis Interbody System implants are made from (polyetheretherketone) PEEK-OPTIMA® (ASTM F2026). As PEEK-OPTIMA is radiolucent, radiographic markers are included in the distal and proximal ends of the PEEK implants. The markers consist of tantalum wires and beads (ASTM F560) that are press-fit into small holes in the implant.

Patient-contacting, reusable instruments for use with the Ardis implants are manufactured from stainless steel and may include an aluminum titanium nitride (AlTiN) PVD and/or titanium nitride (TiN) PVD coating.

Sterility, Implants and Instruments: Ardis implants are gamma sterilized and provided to the end user in sterile packaging.

The associated instruments and perforated instrument cases for use with the Ardis implants are supplied non-sterile and must be sterilized by the healthcare facility prior to use.

Summary of Performance Testing:

A simulated surgical evaluation was conducted using a cadaver specimen to verify that the design of the Ardis Interbody System and associated instruments meet documented user needs and intended use. All instruments in the system were evaluated during the course of the procedure. The function, performance, and conformance to user needs and intended use were validated based on responses received from the participating healthcare professionals. All responses met the established acceptance criteria.

Substantial Equivalence:

Zimmer Spine considers the subject Ardis Interbody System product performance to be substantially equivalent to its predicate device, Ardis Spacer (K073202) because there are no changes to the intended use, design, materials or function.

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

January 30, 2014

Zimmer Spine, Incorporated
Ms. Michelle Lenz
Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K133184
Trade/Device Name: Ardis® Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 8, 2013
Received: October 17, 2013

Dear Ms. Lenz:

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 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 D Devlin -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 on last page.

510(k) Number *(if known)*
K133184

Device Name
Ardis® Interbody System

Indications for Use *(Describe)*
The 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 Ardis Interbody System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

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)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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