JUL 0 2 2014

510(k) Summary

Endoskeleton® TL IBD

June 5, 2014

Company: Titan Spine, LLC
6140 West Executive Drive, Suite A
Mequon, WI 53092, USA

Establishment Registration: 3006340236

Primary Contact: Christine Scifert
Phone: 901-831-8053

Company Contact: Jane Rodd
Phone: 866-822-7800
Fax: 262-242-7802

Trade Name: Endoskeleton® TL Interbody Fusion Device

Common Name: Intervertebral fusion device with bone graft, lumbar

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)

Panel: 87- Orthopedic

Product Code: MAX

Device Description:

The Endoskeleton® TL Interbody Fusion Device (IBD) implants are available in a various sizes with a variety of lordotic angles (0, 7 or 12 degrees), to accommodate patient anatomy. Lengths range from 40 to 60mm, widths from 18 to 26m and heights range from 8 to 16mm. Endoskeleton® TL IBD implants are intended for treatment in Lateral Lumbar Interbody Fusion used in single placement treatment placed across the disc space, and are designed with a large hollow region in the center to house bone graft material. The new bone formation through the implant is intended to provide long-term structural support and biologic fusion at the implanted disc space. The design incorporates "windows" through the implant to permit visualization of the graft material and over time formation of new bone. The superior and inferior surfaces are acid etched to improve fixation to the adjacent bone.

An implant holding feature has been incorporated into the trailing surface of the implant to mate with the implant holder, and to facilitate placement of the implant into the interbody space. All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI).

Indications for Use:
The Endoskeleton® TL IBD is indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. This device is intended for use supplemental fixation systems cleared for use in the lumbar spine. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients with non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft bone.

Substantial Equivalence:
The subject Endoskeleton® TL IBD components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the following interbody devices, previously cleared by the FDA:

- Titan Spine: Endoskeleton® TO – K102067
- Titan Spine: Endoskeleton(r) TA VBR – K032812
- Nuvasive XLIF – K071795

The Indications for Use, Materials, and Geometry for predicate devices are all inclusive of the subject device. The difference between the subject and predicate devices are different sizes and geometry. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
Mechanical testing, including static compression, static compression-shear, static torsion, subsidence, expulsion, dynamic compression, dynamic compression-shear, and dynamic torsion have been performed per ASTM F2077 and ASTM F2267 on the subject Endoskeleton® TL IBD and the results have shown them to be substantially equivalent to the predicate interbody devices.

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

July 2, 2014

Titan Spine, LLC
% Ms. Christine Scifert
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K140055
Trade/Device Name: Endoskeleton® TL Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 5, 2014
Received: June 6, 2014

Dear Ms. Scifert:

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 on last page.

510(k) Number *(if known)*

K140055

Device Name

Endoskeleton® TL Interbody Fusion Device

Indications for Use *(Describe)*

The Endoskeleton® TL IBD is indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. This device is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients with non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft bone.

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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PRAStaff@fda.hhs.gov

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