DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 6, 2017

Titan Spine, LLC
% Ms. Christine Scifert
Executive VP
MRC/X, LLC
6075 Poplar Ave.
Memphis, Tennessee 38119

Re: K170399
Trade/Device Name: Endoskeleton® TO Interbody Fusion Device (IBD)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 31, 2017
Received: June 5, 2017

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,

Vincent J. 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 below.

510(k) Number *(if known)*
K170399

Device Name
Endoskeleton® TO Interbody Fusion Device (IBD)

Indications for Use *(Describe)*
The ENDOSKELETON® TO Interbody Fusion Device is indicated for use 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. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Endoskeleton® TO Interbody Fusion Device (IBD) System

July 5, 2017

Company:	Titan Spine, LLC 6140 W. Executive Drive, Suite A Mequon, WI 53092, USA
Establishment Registration:	3006340236
Primary Contact:	Christine Scifert Phone: 901-831-8053
Company/Secondary Contact:	Jane Rodd Phone: 866-822-7800 Fax: 262-242-7802
Trade Name:	Endoskeleton® TO Interbody Fusion Device (IBD)
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
Primary Predicate:	Titan Spine, LLC Endoskeleton® TO Interbody Fusion Device (IBD) (K141953)
Secondary Predicates:	Titan Spine, LLC Endoskeleton® TO Interbody Fusion Device (IBD) (K102067) K2M, Inc Cascadia Interbody System (K150481 & K160125) DePuy Spine Brantigen Lumbar I/F Cage® with VSP® Spine System (P960025) Surgical Dynamics Ray Threaded Fusion Cage (P950019)

Device Description:
This traditional 510(k) is intended to add additional products to the Endoskeleton® TO System that have been additively manufactured from titanium alloy.

The Endoskeleton® TO Interbody Fusion Device implants are available in a variety of sizes for treatment in Posterior Lumbar Interbody Fusion (PLIF) to accommodate patient anatomy and are designed with a large hollow region in the center to house autograft bone material.
The Endoskeleton® TO Interbody Fusion Device is offered with or without nanoLOCK® Surface Technology. The nanoLOCK® Surface Technology is identical to the previously cleared product (K141953), which is a microscopic roughened surface with nano-scale features. The version without nanoLOCK® Surface Technology has a macro surface roughness.

The implant system must be used with supplemental fixation for stabilizing the implants when placed in the interbody space.

The implants are composed of medical grade titanium alloy (Ti 6Al-4V ELI) per ASTM F136 and ASTM F3001.

The components included in this submission for additive manufacturing are sterile only.

Indications for Use:
The ENDOSKELETON® TO Interbody Fusion Device is indicated for use 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. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Substantial Equivalence:
The subject Endoskeleton® TO IBD is comprised of additively manufactured implants as a line addition to Titan Spine's previously cleared Endoskeleton® TO IBD (K102067) and Endoskeleton® TO IBD with nanoLOCK®(K141953). The subject IBD implants will only be offered sterile and will have part numbers with both the manufactured macro roughened surface and nanoLOCK® Surface Technologies.

The subject components are substantially equivalent to the predicate Endoskeleton® TO System implants. The subject components are also similar in indications, geometry, and additive manufacturing to the secondary predicate K2M Cascadia Interbody System (K150481 & K160125). Additional predicates included the DePuy Spine Brantigen Lumbar I/F Cage® with VSP® Spine System (P960025) and Surgical Dynamics Ray Threaded Fusion Cage (P950019).

Technological Characteristics

There are no changes between the predicate devices and the subject devices with respect to indications for use, overall design, and materials. The only difference to the currently marketed devices is the change in manufacturing process.

Performance Testing:

Mechanical testing was performed to demonstrate substantial equivalence in mechanical strength between the devices previously cleared and the subject devices that are additively manufactured. The following mechanical testing was conducted: Static Axial Compression, Dynamic Axial Compression, Static Compression Shear, Dynamic Compression Shear, and Static Torsion per ASTM F2077; Subsidence per ASTM F2267, and Expulsion. Biocompatibility and cleaning validations were completed in compliance with ISO 10993. Finally, bacterial endotoxin testing was conducted compliant to AAMI ST72. The testing supports that the Endoskeleton® TO devices are adequate for the intended use and substantially equivalent to the predicate systems.

Conclusion:

The subject Endoskeleton® TO IBD is comprised of additively manufactured implants as a line addition to Titan Spine's previously cleared Endoskeleton® TO IBD (K102067) and Endoskeleton® TO IBD with nanoLOCK®(K141953). The testing supports that the Endoskeleton® TO devices are adequate for the intended use and substantially equivalent to the predicate systems. Specifically, the Endoskeleton® TO System implants were determined to be substantially equivalent the predicate Endoskeleton® TO System implants. The subject components are also similar in indications, geometry, and additive manufacturing to the secondary predicate K2M Cascadia Interbody System (K150481 & K160125). Additional predicates included the DePuy Spine Brantigen Lumbar I/F Cage® with VSP® Spine System (P960025) and Surgical Dynamics Ray Threaded Fusion Cage (P950019).