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 28, 2015

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

Re: K142940
Trade/Device Name: Endoskeleton® TCS System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: December 30, 2014
Received: December 31, 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" (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 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,

Lori A. Wiggins -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)*
K142940

Device Name
Endoskeleton(R) TCS System

Indications for Use *(Describe)*
The Endoskeleton® TCS System is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone. The device is a stand-alone system when used with Endoskeleton® TCS integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared in the cervical spine.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Endoskeleton® System
January 27, 2015

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® TCS System

Common Name: Intervertebral Body Fusion Device with Integrated Fusion Cervical
Intervertebral Fusion Device with Bone Graft, Cervical

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: OVE ODP

Predicate Devices: **Primary Predicate**
Titan Spine Endoskeleton® TC (K100889 S.E. July 29, 2010)

Additional Predicates
K2M Chesapeake Spinal System (K133494 S.E. June 10, 2014)
Surgicraft STALIF™ C (K072415 S.E. January 25, 2006)
Centinel Spine STALIF® (K120819 S.E. August 31, 2012)
LDR Spine Cervical Interbody Fusion System (K091088 S.E. July 14, 2009)
LDR Spine Cervical Interbody Fusion System – ROI-C Lordotic Implants (K113559 S.E. December 29, 2011)
Medtronic PEEK PREVAIL® Cervical Interbody Device (K113252 S.E.

January 17, 2012)
Medtronic PEEK PREVAIL™ Cervical Interbody Device (K073285 S.E. May 15, 2008)

Device Description:

The Endoskeleton® TCS Interbody Fusion Device (IBD) implants are available in a variety of sizes with a variety of lordotic angles, to accommodate patient anatomy. Endoskeleton® TCS IBD implants are intended for treatment in Cervical Interbody Fusion procedures and are used as single placement devices in the disc space, and are designed with a large hollow region in the center to house autograft bone. 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.

The device is a stand-alone system when used with Endoskeleton® TCS integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared in the cervical spine.

An implant holding feature has been incorporated into the anterior 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® TCS System is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone. The device is a stand-alone system when used with Endoskeleton® TCS integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared in the cervical spine.

Substantial Equivalence:

The subject Endoskeleton® TCS IBD is substantially equivalent to Titan Spine's previously cleared Endoskeleton® TC (K100889 S.E. July 29, 2010), K2M Chesapeake Spinal System (K133494 S.E. June 10, 2014), Surgicraft STALIF™ C (K072415 S.E. January 25, 2006), Centinel Spine STALIF® (K120819 S.E. August 31, 2012), LDR Spine Cervical Interbody Fusion System (K091088 S.E. July 14, 2009), LDR Spine Cervical Interbody Fusion System – ROI-C Lordotic Implants, (K113559 S.E. December 29, 2011), Medtronic PEEK PREVAIL® Cervical Interbody Device (K113252 S.E. January 17, 2012) and Medtronic PEEK PREVAIL™ Cervical Interbody Device (K073285 S.E. May 15, 2008).

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® TCS IBD and predicate devices. The resulting data from testing demonstrated that the Endoskeleton® TCS IBD was substantially equivalent to the predicate interbody devices identified in the substantial equivalence section.

Conclusion:

There are insignificant differences between the subject Endoskeleton® TCS IBD and the predicates. The Indications for Use, Materials, and Geometry for predicate devices are all inclusive of the subject device. The difference between the subject Endoskeleton® TCS IBD and the Endoskeleton® TC IBD is that the subject allows for use of screws for fixation and various dimensions. The difference between the subject and the additional predicate devices include dimensions. Testing shows that the Endoskeleton® TCS IBD performs equivalent to the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.