



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

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

October 9, 2015

Re: K151596

Trade/Device Name: Endoskeleton® TCS Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: September 3, 2015
Received: September 8, 2015

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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K151596

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Device Name

Endoskeleton(R) TCS Interbody Fusion Device

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)

510(k) Summary
Endoskeleton® System
October 6, 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 Interbody Fusion Device

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

Primary Predicate: Titan Spine Endoskeleton® TCS (K142940 S.E. January 28, 2015)

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 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 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.

All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI).

The primary modification being made in this submission is that the hex size on the screws is being changed from T6 to T8 and as a result the heights now range from 13 – 21.35mm. As a result, there was a small change to the overall length of the screws and a change to the instruments associated with the hex update.

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® TCS IBD (K142940 S.E. January 28, 2015).

The primary modification being made in this submission is that the hex size on the screws is being changed from T6 to T8 and as a result the heights now range from 13 – 21.35mm. As a result, there was a small change to the overall length of the screws and a change to the instruments associated with the hex update. The Indications for Use, materials, and geometry of the IBD devices and the locking collar are identical to the predicate devices. An engineering rationale was provided in lieu of performance testing because these modifications do not impact the overall function of the device and the screw thread length is identical to the predicate. The change in height is due to a small increase in the height of the head of the screw, which does not impact testing. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.