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

August 6, 2019

Re: K191565
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
Dated: July 17, 2019
Received: July 19, 2019

Dear Christine 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Melissa Hall
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191565

Device Name
Endoskeleton® TCS Interbody Fusion Device

Indications for Use *(Describe)*
The Endoskeleton® TCS Interbody Fusion Device is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as 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 or allograft bone comprised of cancellous and/or corticocancellous bone. The device is a stand-alone system when used with Endoskeleton® TCS Interbody Fusion Device integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared for 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary
Endoskeleton® TCS Interbody Fusion Device
July 17, 2019

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

Establishment Registration: 3006340236

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

Company Contact: Kelly McDonnell
Phone: 866-822-7800
Fax: 262-242-7802

Trade Name: Endoskeleton® TCS Interbody Fusion Device

Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: OVE

Predicate Devices:

Primary Predicate:

Titan Spine Endoskeleton® TCS Interbody Fusion Device - K142940, K153122, K173535, & K183557

Secondary Predicate:
Life Spine Pro-Link Ti Stand Alone Cervical Spacer System - K180642

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 have been acid etched through a previously cleared process called nanoLOCK™ (MMN™) to improve fixation to the adjacent bone.

The purpose of this special 510(k) submission is to add a plate to the Endoskeleton® TCS System. The ENDOSKELETON® TCS Plate Device (Plate) is compatible with the ENDOSKELETON® TCS Interbody Fusion Device product family. The design incorporates a locking screw to secure the Plate to the Interbody Fusion Device and is engaged after the plate is placed on the anterior face of the ENDOSKELETON® TCS Interbody Fusion Device to resist the integrated screws from backing out. The system includes a holding feature on the Plate to mate with the inserter to facilitate placement onto the ENDOSKELETON® TCS Interbody Fusion Device implant. Use of this plate is an enhancement to the existing Endoskeleton® TCS system and, as such, is optional with the Endoskeleton® TCS Interbody Fusion Device and does not qualify as supplemental fixation. The subject plate does not include nanoLOCK® (MMN™) surface treatment, as it does not interface with the bone.

The construct 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) and may be provided either sterile or non-sterile. The subject Endoskeleton® TCS Plate is only provided sterile by gamma irradiation.

Indication for Use:

The ENDOSKELETON® TCS Interbody Fusion Device is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as 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 or allograft bone comprised of cancellous and/or corticocancellous bone. The device is a stand-alone system when used with ENDOSKELETON® TCS Interbody Fusion Device integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

Substantial Equivalence:

The subject Endoskeleton® TCS IBD is substantially equivalent to the following:

Primary Predicate: Titan Spine - Endoskeleton® TCS Interbody Fusion Device (K142940, S.E. 01/28/2015; K153122, 12/14/2015; S.E. K173535, S.E. 02/13/2018; and K183557; S.E. 02/11/2019).

Secondary Predicate: Life Spine Pro-Link Ti Stand Alone Cervical Spacer System (K180642, S.E. 05/10/2018)

The subject Endoskeleton® TCS Plate is manufactured from titanium (Ti6Al4V ELI) and is intended to be used as an intervertebral body fusion device only in conjunction with the Endoskeleton® TCS IBDs and Integrated Screws, similar to the predicate devices. The subject plate also shares similar indications for use, geometry, and construction with the predicate devices

Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Performance bench testing, including locking plate resistance to screw push-out and retention force of the plate holder, was performed to demonstrate substantial equivalence.

Conclusion:

Based upon the information contained in this submission and the similarities of the subject and predicate devices, the subject Endoskeleton® TCS Interbody Fusion Deviceis substantially equivalent to the predicate devices.