January 8, 2020

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

Re: K191581
Trade/Device Name: Endoskeleton® TL Interbody Fusion Device, Endoskeleton® TL Hyperlordotic Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: December 6, 2019
Received: December 11, 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,

Brent L. Showalter, PhD
Assistant Director (Acting)
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)*

K191581

Device Name
Endoskeleton® TL Interbody Fusion Device
Endoskeleton® TL Hyperlordotic Interbody Fusion Device

Indications for Use *(Describe)*

The ENDOSKELETON® TL Interbody Fusion Device 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. The device must be used with supplemental fixation that has been cleared by the FDA 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 previous non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate.

The ENDOSKELETON® TL Hyperlordotic Interbody Fusion Device ($\geq 16^{\circ}$) 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the ENDOSKELETON® TL Hyperlordotic Interbody Fusion Device. Patients with previous non-fusion spinal surgery at the involved level(s) may be treated with the device. The Interbody Device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft bone marrow aspirate, or a combination thereof. The ENDOSKELETON® TL Hyperlordotic Interbody Fusion Devicemust be used with an integrated Lateral Plate and Bone Screw and additionally must be used with posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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® TL Interbody Fusion Device
Endoskeleton® TL Hyperlordotic Interbody Fusion Device
January 7, 2020

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® TL Interbody Fusion Device
Endoskeleton® TL Hyperlordotic Interbody Fusion Device

Common Name: Intervertebral Body Fusion Device with Bone Graft, Lumbar
Intervertebral Fusion Device With Integrated Fixation, Lumbar

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: MAX, OVD

Predicate Devices:

Primary Predicate:

Titan Spine Endoskeleton® TAS / TASh – K163269

Secondary Predicates:
Endoskeleton® TL Interbody Fusion Device – K140055
Endoskeleton® TO Interbody Fusion Device – K170399
Endoskeleton® TA Interbody Fusion Device – K080615
Surgicraft STAFLIF TT – K073109
Endoskeleton® Interbody Fusion Devices - K192018

Reference Predicates:
Titan Spine Allograft Indications update – K183557
Titan Spine Sterile TAS / TCS screws – K173535

Titan Spine Sterile only – K142589

Device Description:

The ENDOSKELETON® TL Interbody Fusion Device implants are available in a variety of lengths, widths, and heights for treatment in Lateral Lumbar Interbody Fusion and are designed with a large hollow region in the center to house autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone, demineralized allograft bone marrow aspirate, or a combination thereof. The new bone formation through the implant is intended to provide long-term structural support and fusion at the implanted disc space. The design incorporates "windows" through the implant to permit visualization of device placement and over time formation of new bone. The superior and inferior surfaces include either the Chemtex® surface treatment or nanoLOCK® surface treatment (MMN™) designed to improve fixation to the adjacent bone. The nanoLOCK® surface technology (MMN™) provides a microscopic roughened surface with nano-scale features. The implants are composed of ASTM F136 Ti 6Al-4V ELI titanium alloy and provided either sterile or non-sterile. An implant holding feature has been incorporated into the trailing surface of the implant to mate with the implant inserter and to facilitate placement of the implant into the interbody space.

The subject submission introduces the ENDOSKELETON® TL Hyperlordotic Interbody Fusion Devices are available in a variety of lengths, widths, and heights for treatment in Lateral Lumbar Interbody Fusion and are designed with a large hollow region in the center to house autograft or allograft bone comprised of cancellous and/or corticocancellous bone. The design incorporates "windows" through the Interbody Device to permit visualization of the Interbody Device placement and over time formation of new bone. The new bone formation through the Interbody Device is intended to provide long-term structural support and fusion at the implanted disc space. The Interbody Device is treated with nanoLOCK® Surface Technology (MMN™) designed to improve fixation to the adjacent bone. The nanoLOCK® Surface Technology (MMN™) provides a microscopic roughened surface with nano-scale features.

The subject submission also includes Lateral Plate and Bone Screws which are available in a variety of sizes for stabilizing the Interbody Device. The Lateral Plate has one or two hole(s) for receiving integrated Bone Screws and a feature for attachment to the Interbody Device. The Lateral Plate incorporates a lock cover to resist the integrated Bone Screws from backing out. Holding features have been incorporated into the Interbody Device and associated device components to facilitate placement of the system into the interbody space. The Interbody Device and associated device components are composed of ASTM F136 or ASTM F3001 Ti6Al4V ELI titanium alloy and provided sterile.

Indication for Use:

The ENDOSKELETON® TL Interbody Fusion Device 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. The device must be used with supplemental fixation that has been cleared by the FDA 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 previous non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft

bone and/or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate.
The ENDOSKELETON® TL Hyperlordotic Interbody Fusion Device (≥ 16˚) 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the ENDOSKELETON® TL Hyperlordotic Interbody Fusion Device. Patients with previous non-fusion spinal surgery at the involved level(s) may be treated with the device. The Interbody Device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft bone marrow aspirate, or a combination thereof. The ENDOSKELETON® TL Hyperlordotic Interbody Fusion Devicemust be used with an integrated Lateral Plate and Bone Screw and additionally must be used with posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine.

Substantial Equivalence:

Primary predicate Endoskeleton TAS / TAS Hyperlordotic (K163269), Secondary predicates including Endoskeleton TL (K140055), Endoskeleton TO (K170399), Endoskeleton TA (K080615), Endoskeleton® Interbody Fusion Devices (K192018) and Centinel Spine / Surgicraft STAFLIF TT (K073109) and Reference predicates include Titan Spine Allograft indications update (K183557), Titan Spine sterile TAS/ TCS screws (K173535), and Titan Spine sterile only (K142589).

The subject devices share similar indications for use, geometry, material, manufacturing processes 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:

The subject Endoskeleton® TL and TL Hyperlordotic device constructs underwent static and dynamic testing in accordance with ASTM F2077-18 and ASTM F2267-04(R18), where testing was performed on the worst-case construct. The worst-case bone screw configurations were additionally tested per ASTM F543-17. Particulate and wear analysis on dynamically loaded specimens was conducted per ASTM F1877-16. Bacterial endotoxin testing (LAL) was conducted for these devices.

Conclusion:

Based upon the information contained in this submission and the similarities of the subject and predicate devices, the subject Endoskeleton® TL Interbody Fusion Device and Endoskeleton® TL Hyperlordotic Fusion Devices are substantially equivalent to the predicate devices.