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

August 29, 2019

Re: K192054
Trade/Device Name: Endoskeleton® TAS Plate
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 30, 2019
Received: July 31, 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)*
K192054

Device Name
Endoskeleton® TAS Plate

Indications for Use *(Describe)*

The ENDOSKELETON® TAS 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. 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 nonoperative treatment prior to treatment with the devices. The device is a standalone system that is intended to be used with the bone screws provided and requires no additional supplementary fixation. The Device 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.

Hyperlordotic Devices ≥16˚: The ENDOSKELETON® TAS 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 devices. The device 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® TAS Hyperlordotic Interbody Fusion Device must be used with a posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine must be used with a 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® TAS Plate
August 28, 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® TAS Plate

Common Name: 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: OVD

Predicate Devices:

Primary Predicate:

Titan Spine Endoskeleton® TAS Interbody Fusion Device – K111626, K141953, K142589, K163269, K173535, K183557, and K192018

Secondary Predicate:
Life Spine Dyna-Link Elite Stand-Alone Anterior Lumbar System – K180215

Device Description:
The ENDOSKELETON® TAS and ENDOSKELETON® TAS Hyperlordotic Interbody Fusion device implants are available in a variety of Anterior Lumbar Interbody Fusion (ALIF) sizes with a variety of lordotic angles, to accommodate patient anatomy; Hyperlordotic implants are those defined by a lordotic angle ≥16˚. Implants are designed with a large hollow region in the center to house autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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 the graft material and over time formation of new bone. The superior and inferior surfaces of the IBDs have been acid etched through a previously cleared process called Chemtex® and the IBDs may have also received Titan Spine's 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 implant system includes integrated fixation (screws) for stabilizing the implants when placed in the interbody space. An implant holding feature has been incorporated into the trailing surface of the implant to mate with the implant holder, and to facilitate placement of the implant into the interbody space. Screws include internal hex drive features matched to instrumentation for implantation. All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) and may be provided either sterile or non-sterile.

The purpose of this special 510(k) submission is to add a plate to the Endoskeleton® TAS and TAS Hyperlordotic System. The ENDOSKELETON® TAS Plate is available in a variety of sizes corresponding to the sizes of ENDOSKELETON® TAS and ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device implants. The Plate design incorporates a lock to secure it to the Interbody Fusion Device implant and is engaged after the plate is placed on the anterior face of the ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device implant 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® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion device implant. The subject plate does not include nanoLOCK™ (MMN™) surface treatment, as it does not interface with the bone. The subject Endoskeleton® TAS Plate is only provided sterile by gamma irradiation.

ENDOSKELETON® TAS Plate resists integrated screws from backing out. These plates do not qualify as supplemental fixation and may only be used with ENDOSKELETON® TAS and ENDOSKELETON® TAS Hyperlordotic Interbody fusion devices 12mm and above.

Indication for Use:

The ENDOSKELETON® TAS 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. 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 nonoperative treatment prior to treatment with the devices. The device is a standalone system that is intended to be used with the bone screws provided and requires no additional supplementary fixation. The Device 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.

Hyperlordotic Devices ≥16˚: The ENDOSKELETON® TAS 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 devices. The device 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® TAS Hyperlordotic Interbody Fusion Device must be used with a posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine must be used with a posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine.

Substantial Equivalence:

The subject Endoskeleton® TAS 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® TAS and TAS Hyperlordotic 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.

Technological Characteristics:

The modification for this Special 510(k) includes only the addition of a new plate to prevent screws from backing out. The subject Endoskeleton® TAS Plate is manufactured from titanium (Ti6Al4V ELI) and is intended to be used only in conjunction with the Endoskeleton® TAS and TAS Hyperlordotic IBDs and Integrated Screws as an intervertebral body fusion device, similar to the predicate devices. The subject plate also shares similar indications for use, geometry, and construction with the predicate devices.

Performance Testing:

Performance bench testing, including locking plate resistance to screw push-out, 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® TAS Plate is substantially equivalent to the predicate devices.