February 13, 2018

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

Re: K173535
Trade/Device Name: Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TAS Hyperlordotic Interbody Fusion Device, Endoskeleton® TCS Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, OVD
Dated: January 22, 2018
Received: January 23, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173535

Device Name
Endoskeleton® TAS Interbody Fusion Device, ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device and Endoskeleton® TCS Interbody Fusion Device

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. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

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. 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.

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 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)

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510(k) Summary
Endoskeleton® TAS, TAS Hyperlordotic *& TCS Interbody Fusion Device - Screws*
February 9, 2018

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® TAS Interbody Fusion Device
Endoskeleton® TAS Hyperlordotic Interbody Fusion Device
Endoskeleton® TCS Interbody Fusion Device

Common Name: Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Intervertebral Body 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, OVD, ODP

Predicate Devices:

Primary Predicate
Titan Spine Endoskeleton® TAS Interbody Fusion Device (K163269, S.E. 04/13/2017)

Additional Predicates
Titan Spine Endoskeleton® TCS System (K153122, S.E. 12/14/2015)
Titan Spine Endoskeleton® System Interbody Fusion Device (K142589, S.E. 10/17/2014)

Device Description:
The Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TAS Hyperlordotic Interbody Fusion Device and Endoskeleton® TCS Interbody Fusion Device screws that are the subject of the present submission have been previously cleared as non-sterile. This Special 510(k) submission seeks clearance for the subject Endoskeleton® screws to be provided sterile by gamma irradiation. The current

Endoskeleton family is an interbody and vertebral body system comprised of a variety of sizes and geometries to accommodate various patient anatomy and pathology. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI). The center of the implant is hollow and is to be filled with autograft material. The design incorporates "windows" through the implant to permit visualization of the graft material and, over time, formation of new bone.

The predicate Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TAS Hyperlordotic Interbody Fusion Device and Endoskeleton® TCS Interbody Fusion Device screws (K163269 & K153122) are provided non-sterile. The secondary predicate is a previous clearance by Titan Spine for interbody and vertebral body devices (K142589) that are sterilized by gamma irradiation. The subject screws are identical to the primary predicate in all ways except sterility. The subject devices are provided sterile via gamma irradiation, identical to the sterilization method for the secondary predicate Endoskeleton® implants cleared in K148529.

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. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

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. 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.

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 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 predicate Endoskeleton® families include the Endoskeleton® TCS System – K153122 and Endoskeleton® TAS Interbody Fusion Device – K163269, both of which contain non-sterile implants. The secondary predicate in which Titan Spine previously obtained clearance for gamma sterilized devices is K142589. The intended use, indications for use, material, surgical technique, material, surface treatment and dimensions of the subject devices are identical predicate devices. The subject devices

differ from the predicate devices in the method of sterilization. The predicate screws are non-sterile and steam sterilized by the end user. The subject screws are provided sterile via gamma irradiation, identical to the method cleared for the devices in in K142589 and K163269.

Technological Characteristics:

There are no changes between the predicate devices and the subject devices with respect to indications for use, design, dimension, surface treatment and materials. The only difference to the currently marketed fixation devices is the change in sterilization. The fixation components are provided sterile via gamma irradiation as opposed to the predicates that are provided non-sterile.

Performance Testing:

Sterilization validation and pyrogen testing was completed to verify that the subject devices are effectively sterilized via gamma irradiation.

Biocompatibility:

All implant components of the Endoskeleton® TAS and TCS Screws are made from medical grade titanium (Ti6AL4V-ELI) alloy per ASTM F-136. The devices are patient contacting and are implanted for durations greater than 30 days.

Based on the history of the material used in the device, ASTM F-136 and ISO 10993-1 and testing results Titan Spine has concluded that no further biocompatibility testing is required.

Conclusion:

The subject Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TAS Hyperlordotic Interbody Fusion Device and Endoskeleton® TCS Interbody Fusion Device families are a line addition to Titan Spine's previously cleared Endoskeleton® TAS Interbody Fusion Device (K142589) and Endoskeleton® TCS Interbody Fusion Device (K151596). The testing supports that the Endoskeleton® TAS Interbody Fusion Device and the Endoskeleton® TCS Interbody Fusion Device families are adequate for the intended use and substantially equivalent to the predicate systems.