DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 13, 2017

Titan Spine, LLC
% Christine Scifert
Managing Partner
Memphis Regulatory Consulting (MRC-X), LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K163269
Trade/Device Name: Endoskeleton® TAS Interbody Fusion Device / Endoskeleton® TAS Hyperlordotic Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 15, 2017
Received: March 20, 2017

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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K163269

K163269

Device Name

Endoskeleton® TAS Interbody Fusion Device / Endoskeleton® TAS Hyperlordotic 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. 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 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.

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.

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

Traditional 510(k)
Endoskeleton® TAS System
March 16, 2017

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

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

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: OVD

Predicate Devices:

Primary Predicate
NuVasive Inc. Brigade Hyperlordotic System (K123045 S.E. June 16, 2013)

Additional Predicates
Titan Spine Endoskeleton® TAS (K111626 S.E. September 9, 2011)
Titan Spine Endoskeleton® TA (K080615 S.E. June 17, 2008)
Titan Spine nanoLOCK® Surface Technology (K141953 S.E. October 27, 2014)
Centinel Spine/Surgicraft STALIF TT (K073109 S.E. June 4, 2008)

Device Description:

The Endoskeleton® TAS Interbody Fusion Device 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 ≥ 16^0. Implants are designed with a large hollow region in the center to house autograft bone material. 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 include either the previously cleared Chemtex® surface treatment or previously cleared nanoLOCK® surface treatment to improve fixation to the adjacent bone. The nanoLOCK ®surface technology 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 (Ti6A14V-ELI).

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 non-operative 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.

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.

Substantial Equivalence:
The Endoskeleton®TAS Hyperlordotic IBD is substantially equivalent to the NuVasive Inc. Brigade Hyperlordotic System (K123045 S.E. June 16, 2013), Titan Spine's previously cleared Endoskeleton®TAS (K111626 S.E. September 9, 2011& K141953 S.E. October 27, 2014), Titan Spine Endoskeleton® TA (K080615 S.E. June 17, 2008) and Centinel Spine/Surgicraft STALIF TT (K073109 S.E. June 4, 2008).

Performance Testing:
Mechanical testing, including static compression, static compression shear, dynamic compression, dynamic compression-shear, subsidence and expulsion have been performed per ASTM F2077 and ASTM 2267 on the subject Endoskeleton® TAS Hyperlordotic IBD and the predicate devices. In addition, a cadaver study was performed and radiographic and CAD analysis was performed.

The resulting data from testing demonstrates that the Endoskeleton® TAS and nanoLOCK® TAS Hyperlordotic Interbody Fusion Devices are substantially equivalent to the predicate interbody devices identified in the substantial equivalence section.

Conclusion:

The subject submission introduces a Hyperlordotic IBD to the Endoskeleton® TAS Interbody Fusion System. The Indications for Use, materials and geometry of the subject device is similar to the predicate devices. Mechanical testing demonstrates that the Endoskeleton® TAS Hyperlordotic IBD is substantially equivalently compared to predicate devices. Thus, it can be concluded that the subject device does not raise new questions about safety and effectiveness.