February 11, 2019

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

Re: K183557
Trade/Device Name: Endoskeleton® TA Interbody Fusion Device, Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TO Interbody Fusion Device, Endoskeleton® TT Interbody Fusion Device, Endoskeleton® TC Interbody Fusion Device, Endoskeleton® TCS Interbody Fusion Device, Endoskeleton® TL Interbody Fusion Device, Endoskeleton® TA Vertebral Body Replacement (VBR) Device
Regulation Number: 21 CFR 888.3080
21 CFR 888.3060
Regulation Name: Intervertebral Body Fusion Device
Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: ODP, MAX, OVD, OVE, MQP
Dated: January 21, 2019
Received: January 23, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Melissa Hall -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)*

K183557

Device Name
ENDOSKELETON® TA Interbody Fusion Device

Indications for Use *(Describe)*

The ENDOSKELETON® TA 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 intended to 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). ENDOSKELETON® TA is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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."

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)*

K183557

Device Name
ENDOSKELETON® TAS 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 or allograft bone comprised of cancellous and/ or corticocancellous 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 or allograft bone comprised of cancellous and/ or corticocancellous 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)

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."

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)*

K183557

Device Name
ENDOSKELETON® TO Interbody Fusion Device

Indications for Use *(Describe)*

The ENDOSKELETON® TO 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 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). It is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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."

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)*

K183557

Device Name
ENDOSKELETON® TT Interbody Fusion Device

Indications for Use *(Describe)*

The ENDOSKELETON® TT 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 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). It is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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."

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)*

K183557

Device Name
ENDOSKELETON® TC Interbody Fusion Device

Indications for Use *(Describe)*

The ENDOSKELETON® TC Interbody Fusion Device is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The ENDOSKELETON® TC Interbody Fusion Device is indicated to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine and autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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."

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)*

K183557

Device Name
ENDOSKELETON® TCS Interbody Fusion Device

Indications for Use *(Describe)*

The Endoskeleton® TCS Interbody Fusion Device System 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 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.

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."

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)*

K183557

Device Name
ENDOSKELETON® TL 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. This device is intended for use with supplemental fixation systems cleared 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 or allograft bone comprised of cancellous and/ or corticocancellous bone.

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."

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)*
K183557

Device Name
ENDOSKELETON® TA Vertebral Body Replacement (VBR) Device

Indications for Use *(Describe)*
The ENDOSKELETON® TA Vertebral Body Replacement is for use in the thoracolumbar spine (T1 – L5) to replace all or part of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The ENDOSKELETON® TA Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems that has been cleared by the FDA for use in the lumbar spine. The ENDOSKELETON® TA Vertebral Body Replacement may be used with bone graft material and/or allogeneic bone graft.

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® System
February 6, 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: Jane Rodd
Phone: 866-822-7800
Fax: 262-242-7802

Trade Name: Endoskeleton® TA Interbody Fusion Device
Endoskeleton® TAS Interbody Fusion Device
Endoskeleton® TO Interbody Fusion Device
Endoskeleton® TT Interbody Fusion Device
Endoskeleton® TC Interbody Fusion Device
Endoskeleton® TCS Interbody Fusion Device
Endoskeleton® TL Interbody Fusion Device
Endoskeleton® TA Vertebral Body Replacement (VBR) Device

Common Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar
Intervertebral Fusion Device With Bone Graft, Cervical
Intervertebral Fusion Device With Integrated Fixation, Cervical
Intervertebral Fusion Device With Bone Graft, Lumbar
Spinal Vertebral Body Replacement Device

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)
21 CFR 888.3060 (Spinal intervertebral body fixation orthosis)

Panel: 87- Orthopedic

Product Code: ODP, OVD, OVE, MAX, MQP

Predicate Devices: **Primary Predicate:**

HD LifeSciences, LLC Lumbar Interbody System – K170676

Secondary Predicates:
HD LifeSciences, LLC Cervical IBFD System – K180364
NuVasive® Modulus-C Interbody System – K172676

Choice Spine Hawkeye™ Vertebral Body Replacement (VBR) System – K171686
Endoskeleton® TAS and TCS – K173535
Endoskeleton® TO – K170399
Endoskeleton® System (TA IBD and VBR, TO, TT, TAS, TC, TL) – K141953

Device Description:
The current Endoskeleton® system is an interbody and vertebral body family 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. This submission seeks to expand the indications of these devices to include use with allograft material.

The predicate Endoskeleton® System (K173535, K170399, and K141953) is provided either non-sterile or sterile via gamma irradiation. The Endoskeleton® TA VBR (K032812) was initially manufactured and submitted by Orthovita, Inc (Malvern, PA). Titan Spine has the 510(k) and maintains the device listing for the device.

Indication for Use:

The ENDOSKELETON® TA 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 intended to 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). ENDOSKELETON® TA is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

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 or allograft bone comprised of cancellous and/ or corticocancellous 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 or allograft bone comprised of cancellous and/ or corticocancellous 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® TO 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 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). It is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

The ENDOSKELETON® TT 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 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). It is indicated to be used with autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

The ENDOSKELETON® TC Interbody Fusion Device is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The ENDOSKELETON® TC Interbody Fusion Device is indicated to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine and autograft bone or allograft bone comprised of cancellous and/ or corticocancellous bone.

The Endoskeleton® TCS Interbody Fusion Device System 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 integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

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. This device is intended for use with supplemental fixation systems cleared 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 or allograft bone comprised of cancellous and/ or corticocancellous bone.

The ENDOSKELETON® TA Vertebral Body Replacement is for use in the thoracolumbar spine (T1 – L5) to replace all or part of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The ENDOSKELETON® TA Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems that has been cleared by the FDA for use in the lumbar

spine. The ENDOSKELETON® TA Vertebral Body Replacement may be used with bone graft material and/or allogeneic bone graft.

Substantial Equivalence:

Titan Spine has 14 previous clearance related to the predicate Endoskeleton® systems. The most recent clearances for each sub-family are provided below for the primary and secondary predicates:

Primary Predicate:	HD LifeSciences, LLC Lumbar Interbody System – K170676
Secondary Predicates:	HD LifeSciences, LLC Cervical IBFD System – K180364
	NuVasive® Modulus-C Interbody System – K172676
	Choice Spine Hawkeye™ Vertebral Body Replacement (VBR) System – K171686
	Endoskeleton TAS and TCS – K173535
	Endoskeleton TO – K170399
	Endoskeleton® System (TA IBD and VBR, TO, TT, TAS, TC, TL) – K141953

The modification for this Special 510(k) relates only to indications for use.
The intended use, material, surgical technique, surface treatment, sterility, and design of the subject devices are the same as predicate devices. The only change that is the subject of this submission is to change the indication for use with allograft material.

A comprehensive literature review was conducted to assess any additional safety concern for the use of these devices with allograft. The review of the literature concluded that there were no additional risks due to the modification of the indications of these devices to include use with allograft and that these devices are substantially equivalent to the predicate devices.

Technological Characteristics:

The modification for this Special 510(k) relates only to the indications for use. The intended use, material, surgical technique, surface treatment, sterility, and design of the subject devices are the same as predicate devices.

Performance Testing:

No performance testing was required or performed, as this modification for this Special 510(k) relates only to the indications for use.

Biocompatibility:

There are no changes to the Endoskeleton® System materials. The devices are patient contacting and are implanted for durations greater than 30 days. All implant components of the Endoskeleton® devices are made from medical grade titanium (Ti6Al4V-ELI) alloy per ASTM F-136/ISO 5832-3 and ASTM F-3001.

Conclusion:

Based upon the clinical literature contained in this submission and the similarities of the subject and predicate devices, the subject Endoskeleton® system is substantially equivalent to the predicate devices.