May 26, 2021

Medtronic Sofamor Danek USA, Inc.
Kelly McDonnell
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K211258
Trade/Device Name: Endoskeleton TC Interbody System, Endoskeleton TCS Interbody System, Endoskeleton TA Interbody System, Endoskeleton TAS & TAS Hyp Interbody System, Endoskeleton TL Interbody System, Endoskeleton TL Hyp. Interbody System, Endoskeleton TO Interbody System, Endoskeleton TT Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, OVD, OVE
Dated: April 23, 2021
Received: April 26, 2021

Dear Kelly McDonnell:

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
Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TA Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TA Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The Endoskeleton™ TA Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is to be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
Endoskeleton™ TA Interbody System is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TAS and TAS Hyperlordotic Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TAS Interbody System device including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. 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. The Endoskeleton™ TAS Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis and spinal stenosis at one or two adjacent levels, the Endoskeleton™ TAS Interbody System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TAS Hyperlordotic Interbody System (≥16˚) devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with DDD, degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. 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, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TAS Hyperlordotic Interbody System must be used with a posterior supplemental internal spinal fixation 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)

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510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TC Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TC Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The Endoskeleton™ TC Interbody System is indicated to be used with supplemental fixation cleared by the FDA for use in the cervical spine and autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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) Number *(if known)*
K211258

Device Name
Endoskeleton™ TCS Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TCS Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or instability, as confirmed by imaging studies(radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The device is a stand-alone system when used with Endoskeleton™ TCS Interbody System integrated screws. When used without the integrated screws, the Endoskeleton™ TCS Interbody System requires additional supplemental fixation cleared by the FDA 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)

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See PRA Statement below.

510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TL Hyperlordotic Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TL Hyperlordotic Interbody System (≥16˚) devices with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Patients should have received 6 months of non-operative treatment prior to treatment with the Endoskeleton™ TL Hyperlordotic Interbody System. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. The Endoskeleton™ TL Hyperlordotic Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The Interbody Device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TL Hyperlordotic Interbody System must be used with an integrated lateral plate and bone screw and additionally must be used with posterior supplemental internal spinal fixation 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)

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510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TL Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TL Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non- operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TL Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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) Number *(if known)*
K211258

Device Name
Endoskeleton™ TO Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TO Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TO Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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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See PRA Statement below.

510(k) Number *(if known)*
K211258

Device Name
Endoskeleton™ TT Interbody System

Indications for Use *(Describe)*
The Endoskeleton™ TT Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TT Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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

MEDTRONIC Sofamor Danek USA, Inc.

Endoskeleton™ Interbody Systems

26 May 2021

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133

Contact: Kelly McDonnell
Sr. Regulatory Affairs Specialist
Email: kelly.m.mcdonnell@medtronic.com

Date Prepared: April 23, 2021

II. Subject Device

Name of Device:
Endoskeleton™ TA Interbody System
Endoskeleton™ TAS & TAS Hyp. Interbody System
Endoskeleton™ TC Interbody System
Endoskeleton™ TCS Interbody System
Endoskeleton™ TL Interbody System
Endoskeleton™ TL Hyp. Interbody System
Endoskeleton™ TO Interbody System
Endoskeleton™ TT Interbody System

Product Codes: MAX, ODP, OVD, OVE

Common name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

Classification: Class II

III. Predicate Devices:

Predicate 1 (Primary Predicate):

EIT Cellular Titanium® Cages- K201605 (S.E. 07/15/2020)

Predicate 2 (Additional Predicate):

Endoskeleton™ Interbody Systems- K192018 (S.E. 08/13/2019)

Predicate 3 (Additional Predicate):

NuVasive Interbody Systems K203201 (S.E. 01/12/2021)

The predicate devices were not subjected to any Recall.

IV. Description:

The Endoskeleton™ Interbody System implants are available in a variety of sizes and designed with a large hollow region in the center to house autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The design incorporates "windows" through the implant to permit visualization of the graft material and, over time, formation of new bone. Devices incorporate Titan Surface Technologies™, where superior and inferior surfaces include either Chemtex™ or nanoLOCK™ surface treatment (MMN™) designed to improve fixation to adjacent bone. nanoLOCK™ surface technology (MMN™) provides a microscopic roughened surface with nanoscale features. The nanoLOCK™ Surface Technology is specifically engineered to have nano textured features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features *in vitro*. The nanoLOCK™ surface technology demonstrates the elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document. New bone formation through the implant is intended to provide long-term structural support and fusion at the implanted disc space. Implants are composed of ASTM F136 Ti 6Al-4V ELI titanium alloy and are provided either sterile or non-sterile. The Endoskeleton™ TL Hyp. implants are composed of ASTM F3001 Ti 6Al-4V ELI titanium alloy and are provided sterile.

The Endoskeleton™ TAS & TAS Hyp. and Endoskeleton™ TCS Interbody systems include integrated fixation screws for stabilizing the implants when placed in the interbody space. Screws are composed of ASTM F136 Ti 6Al-4V ELI titanium alloy and are provided either sterile or non-sterile.

The Endoskeleton™ Interbody System implants should only be implanted by surgeons experienced in the use of such implants and the required specialized spinal surgery techniques.

V. Indications for use

Endoskeleton™ TA Interbody System

The Endoskeleton™ TA Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The Endoskeleton™ TA Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is to be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Endoskeleton™ TA Interbody System is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Endoskeleton™ TAS & TAS Hyperlordotic Interbody System

The Endoskeleton™ TAS Interbody System devices including those with macro-, micro- and nano-roughened surface textured features devices are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. 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. The Endoskeleton™ TAS Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis and spinal stenosis at one or two adjacent levels, the Endoskeleton™ TAS Interbody System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use

in the lumbar spine in addition to the integrated screws. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Indications for Hyperlordotic Devices ≥16˚

The Endoskeleton™ TAS Hyperlordotic Interbody System (≥16˚) devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with DDD, degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. 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, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TAS Hyperlordotic Interbody System must be used with a posterior supplemental internal spinal fixation cleared by the FDA for use in the lumbar spine.

Endoskeleton™ TC Interbody System

The Endoskeleton™ TC Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The Endoskeleton™ TC Interbody System is indicated to be used with supplemental fixation cleared by the FDA for use in the cervical spine and autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Endoskeleton™ TCS Interbody System

The Endoskeleton™ TCS Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or instability, as confirmed by imaging studies(radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The device is a stand-alone system when used

with Endoskeleton™ TCS Interbody System integrated screws. When used without the integrated screws, the Endoskeleton™ TCS Interbody System requires additional supplemental fixation cleared by the FDA for the cervical spine.

Endoskeleton™ TL Interbody System

The Endoskeleton™ TL Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non- operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TL Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Endoskeleton™ TL Hyperlordotic Interbody System

The Endoskeleton™ TL Hyperlordotic Interbody System (≥16˚) devices with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Patients should have received 6 months of non-operative treatment prior to treatment with the Endoskeleton™ TL Hyperlordotic Interbody System. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. The Endoskeleton™ TL Hyperlordotic Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The Interbody Device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TL Hyperlordotic Interbody System must be used with an integrated

lateral plate and bone screw and additionally must be used with posterior supplemental internal spinal fixation cleared by the FDA for use in the lumbar spine.

Endoskeleton™ TO Interbody System

The Endoskeleton™ TO Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TO Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Endoskeleton™ TT Interbody System

The Endoskeleton™ TT Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TT Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

VI. Comparison of Technological

The subject Endoskeleton™ Interbody System implants have the same intended use, fundamental scientific technology, material, sizing, and

Characteristics with the Predicate Devices

sterilization method as the previously FDA cleared Endoskeleton™ Interbody System predicates. The primary difference between predicate devices and subject devices are:

- The modification to the device description to identify the devices with nanoLOCK™ Surface Technology meet the FDA guidance document definition of nanotechnology.
- The modification to indications to identify that the devices treat instability of the spine through spinal fusion.
- The expansion of indications based on the predicates' cleared indications for EIT Cellular Titanium® Cages- K201605 (S.E. 07/15/2020) and NuVasive Interbody Systems K203201 (S.E. 01/12/2021).

Please refer to the substantial equivalence section of this submission for more details.

Both Subject and Predicate devices are based on the same technological characteristics of providing vertebral stability through fusion for skeletally mature patients with degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis where the instability requires treatment through spinal fusion.

The indications for use are substantially equivalent to the EIT Cellular Titanium® Cages K201605 (S.E. 07/15/2020) and the NuVasive Interbody Systems K203201 (S.E. 01/12/2021). The design features, materials and intended use of the subject devices are substantially equivalent to the previously cleared predicate Endoskeleton™ Interbody Fusion Systems K192018 (S.E. 08/13/2019). Therefore, the technological characteristics of the subject devices are identical to the predicate devices.

VII. Performance Data

Mechanical Testing:

In accordance with, "Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. There is no change to the Endoskeleton™ Interbody System product families' design, manufacturing, materials, nor intended use. Therefore, no new mechanical testing was required for this Submission.

Biocompatibility:

The subject Endoskeleton™ Interbody System implants are permanent implants (> 30 days) and are classified as body contacting devices according to FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The subject implants are manufactured from identical materials as the predicate devices, in accordance with the following standards:

- ASTM F136 – Standard Specification for Wrought Titanium – 6Aluminum – 4Vanadium ELI (Extra-Low-Interstitial) Alloy for Surgical Implants
- ASTM F3001 – Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion

The materials used for manufacturing the subject device have a long history of safe and effective use identical to predicate devices and biocompatibility testing is not required.

VIII. Conclusion:

Based on the supporting information provided in this pre-market notification, the subject Endoskeleton™ Interbody Systems are substantially equivalent to the following predicates:

- Predicate 1 (Primary Predicate) EIT Cellular Titanium® Cervical Cages- K201605 (S.E. 07/15/2020)

- Predicate 2 (Additional Predicate) Endoskeleton™ Interbody Systems- K192018 (S.E. 08/13/2019)
- Predicate 3 (Additional Predicate) NuVasive Interbody Systems K203201 (S.E. 01/12/2021)