September 4, 2025

Medtronic Sofamor Danek USA, Inc.
Pamela Hopkins
International Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K251444
Trade/Device Name: Endoskeleton™ Interbody Systems
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVE, ODP, OVD
Dated: August 1, 2025
Received: August 1, 2025

Dear Pamela Hopkins:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brent Showalter -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251444 ?

Please provide the device trade name(s). ?

Endoskeleton™ Interbody Systems

Please provide your Indications for Use below. ?

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™ TA VBR Interbody System
The Endoskeleton™ TA Vertebral Body Replacement Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are for use in the thoracolumbar spine (T1 – L5) in skeletally mature patients replacing 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 Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The Endoskeleton™ TA Vertebral Body Replacement Interbody System is intended for use with supplemental internal spinal fixation systems cleared by the FDA for use in the lumbar spine. The Endoskeleton™ TA Vertebral Body Replacement Interbody System may 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 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. 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

Medtronic Sofamor Danek USA, Inc.
Endoskeleton™ Interbody Systems – MR Conditional Labeling
September 3, 2025

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

Contact: Pamela Hopkins
Regulatory Affairs Specialist
Email: pamela.a.hopkins@medtronic.com

Trade Name: Endoskeleton™ TA Interbody System
Endoskeleton™ TA VBR Interbody System
Endoskeleton™ TAS & TAS Hyperlordotic Interbody System
Endoskeleton™ TC Interbody System
Endoskeleton™ TCS Interbody System
Endoskeleton™ TL Interbody System
Endoskeleton™ TL Hyperlordotic Interbody System
Endoskeleton™ TO Interbody System
Endoskeleton™ TT Interbody System

Common Name: Intervertebral Body Fusion Device

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral Body Fusion Device)

Panel: 87 Orthopedic

Product Codes: OVE, ODP, MAX, OVD

Predicate Devices: Primary Predicate
Endoskeleton™ Interbody Systems (K211258 S.E. 05/26/2021)

Device 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 Hyperlordotic (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.

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™ TA VBR Interbody System

The Endoskeleton™ TA Vertebral Body Replacement Interbody System devices including those with macro-, micro- and nano-roughened surface textured features are for use in the thoracolumbar spine (T1 – L5) in skeletally mature patients replacing 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 Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The Endoskeleton™ TA Vertebral Body Replacement Interbody System is intended for use with supplemental internal spinal fixation systems cleared by the FDA for use in the lumbar spine. The Endoskeleton™ TA Vertebral Body Replacement Interbody System may 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 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. 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.

Comparison of Technological Characteristics with the Predicate Devices:

The subject Endoskeleton™ Interbody System implants have the same intended use, fundamental scientific technology, material, sizing, and sterilization method as the previously FDA cleared Endoskeleton™ Interbody System predicates. The primary difference between predicate devices and subject devices is the MR Conditional labeling. Please refer to the substantial equivalence section of this submission for more details.

Performance Data:

The subject Endoskeleton™ Interbody devices underwent the following testing to ensure the conditions under which patients with the devices can be safely imaged in the MR environment:

- ASTM Designation F2503-23: "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment" (2023).
- ASTM Designation F2182-19a: "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging" (2019).
- ASTM Designation F2052-21: "Standard Test Method for Measurement of Magnetically Induced Displacement Force on

Medical Devices in the Magnetic Resonance Environment" (2021).

- ASTM Designation F2213-17: "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment" (2017).
- ASTM Designation F2119-24: "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants" (2024).
- PR20066A: "MRI Testing Protocol for Medtronic Spine Titan System: RF heating, Force, Torque, and Image-Distortion", MRIdt Inc. (2020).

Conclusion: Based on the supporting evidence provided in this submission, Medtronic believes the Endoskeleton™ Interbody Systems with MR Conditional labeling are substantially equivalent to the previously cleared Endoskeleton™ Interbody System devices Endoskeleton™ Interbody Systems (K211258 S.E. 05/26/2021).