August 23, 2021

Medtronic Sofamor Danek USA, Inc
Emmarie Halteman
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K192502
Trade/Device Name: Anatomic PEEK™ Cervical Fusion System, Anatomic PEEK™ PTC Cervical Fusion System, Capstone™ Spinal System, Capstone PTC™ Spinal System, Capstone Control™ Spinal System, Capstone Control PTC™ Spinal System, Clydesdale™ Spinal System, Clydesdale PTC™ Spinal System, Cornerstone™ PSR Cervical Fusion System, Crescent™ Spinal System, Crescent™ Spinal System Titanium, Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only), Divergence-L™ Anterior/Oblique Lumbar Fusion System, Elevate™ Spinal System, Perimeter™ Interbody Fusion Device, Pivox™ Oblique Lateral Spinal System, Sovereign™ Spinal System, T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, ODP, OVE, MQP, PLR

Dear Ms. Halteman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 22, 2020. Specifically, FDA is updating this SE Letter as an administrative correction, to update the Indications for Use and labeling.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, Brent.Showalter@fda.hhs.gov.

Sincerely,

Brent Showalter -S

Brent L. 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

January 22, 2020

Medtronic Sofamor Danek USA, Inc
Ms. Emmarie Halteman
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K192502
Trade/Device Name: Anatomic PEEK™ Cervical Fusion System, Anatomic PEEK™ PTC Cervical Fusion System, Capstone™ Spinal System, Capstone PTC™ Spinal System, Capstone Control™ Spinal System, Capstone Control PTC™ Spinal System, Clydesdale™ Spinal System, Clydesdale PTC™ Spinal System, Cornerstone™ PSR Cervical Fusion System, Crescent™ Spinal System, Crescent™ Spinal System Titanium, Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only), Divergence-L™ Anterior/Oblique Lumbar Fusion System, Elevate™ Spinal System, Perimeter™ Interbody Fusion Device, Pivox™ Oblique Lateral Spinal System, Sovereign™ Spinal System, T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, ODP, OVE, MQP, PLR
Dated: November 20, 2019
Received: November 22, 2019

Dear Ms. Halteman:

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,

Brent Showalter -S

Brent Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary
Medtronic Sofamor Danek
Medtronic Intervertebral Body Fusion Spinal Systems
August 2021

Submitter	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact(s)	Emmarie Halteman Regulatory Affairs Specialist Direct Telephone – 901-399-2216
Date Prepared	August 6, 2021
Trade Names	ANATOMIC PEEK™ Cervical Fusion System ANATOMIC PEEK™ PTC Cervical Fusion Spinal System Capstone™ Spinal System Capstone Control™ Spinal System Capstone Control PTC™ Spinal System Capstone PTC™ Spinal System Clydesdale™ Spinal System Clydesdale PTC™ Spinal System Cornerstone™ PSR Cervical Fusion System Crescent™ Spinal System Crescent™ Spinal System Titanium Divergence-L™ Anterior/Oblique Lumbar Fusion System Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only) Elevate™ Spinal System Perimeter Interbody Fusion Device Pivox™ Oblique Lateral Spinal System Sovereign™ Spinal System T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)
Classification Names	Intervertebral Fusion Device with Bone Graft, Lumbar Intervertebral Fusion Device with Integrated Fixation, Lumbar Spinal Vertebral Body Replacement Device Intervertebral Fusion Device with Bone Graft, Cervical Intervertebral Fusion Device with Integrated Fixation, Cervical
Regulatory Class **Regulation Number** **Regulation Name** **Device Product Classification Code**	Class II 888.3080; 888.3060 Intervertebral Body Fusion Device; Spinal Intervertebral Body Fixation Orthosis MAX; OVD; MQP; PLR; ODP; OVE
Predicate Devices	**Primary Predicate:** ARTiC-L™ 3D and ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology — K190959 (S.E. 07/03/2019) **Additional Predicate:**

	Endoskeleton TA Interbody Fusion Device, Endoskeleton TAS and TAS Hyperlordotic 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	K192018 (S.E. 08/16/2019)
	Additional Predicates:	
	ANATOMIC PEEK™ Cervical Fusion System	K112444 (S.E. 11/15/2011); K122037 (S.E. 03/22/2013); K130177 (S.E. 09/23/2013)
	ANATOMIC PEEK™ PTC Cervical Fusion Spinal System	K133653 (S.E. 04/28/2014); K160528 (S.E. 03/28/2016)
	Capstone™ Spinal System	K073291 (S.E. 04/24/2008); K103731 (S.E. 07/18/2011); K121760 (S.E. 08/29/2012); K123978 (S.E. 04/09/2013); K133650 (S.E. 12/20/2013); K151128 (S.E. 08/06/2015)
	Capstone Control™ Spinal System	K120368 (S.E. 04/09/2012); K171107 (S.E. 09/26/2017); K190165 (S.E. 05/06/2019)
	Capstone Control PTC™ Spinal System	K171107 (S.E. 09/26/2017)
	Capstone PTC™ Spinal System	K133205 (S.E. 03/12/2014); K172199 (S.E. 09/19/2017)
	Clydesdale™ Spinal System	K083026 (S.E. 12/29/2008); K100175 (S.E. 06/02/2010); K112405 (S.E. 11/21/2011); K113528 (S.E. 12/20/2011); K132897 (S.E. 12/11/2013); K151128 (S.E. 08/06/2015)
	Clydesdale PTC™ Spinal System	K133205 (S.E. 03/13/2014)
	Cornerstone™ PSR Cervical Fusion System	K100214 (S.E. 06/25/2010); K111264 (S.E. 10/12/2011); K122037 (S.E. 03/22/2013); K153373 (S.E. 01/19/2016)
	Crescent™ Spinal System	K172199 (S.E. 09/19/2017); K171031 (S.E. 07/06/2017); K133216 (S.E. 11/22/2013); K094025 (S.E. 04/26/2010)
	Crescent™ Spinal System Titanium	K172199 (S.E. 09/19/2017); K110543 (S.E. 08/09/2011)
	Divergence-L™ Anterior/Oblique Lumbar Fusion System	K162212 (S.E. 05/19/2017); K150135 (S.E. 06/11/2015)
	Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only)	K142450 (S.E. 10/01/2014); K141599 (S.E. 01/21/2015); K182885 (S.E. 02/06/2019)
	Elevate™ Spinal System	K142559 (S.E. 06/09/2015); K172199 (S.E. 09/19/2017)
	Perimeter Interbody Fusion Device	K090353 (S.E. 09/29/2009); K113642 (S.E. 02/06/2012); K131669 (S.E. 11/01/2013); K132700 (S.E. 09/26/2013); K133645 (S.E. 01/03/2014); K160418 (S.E. 03/07/2016)

	Pivox™ Oblique Lateral Spinal System	K152277 (S.E. 11/13/2015)
	Sovereign™ Spinal System	K091813 (S.E. 11/17/2009); K121982 (S.E. 07/26/2012); K162680 (S.E. 12/14/2016); K172328 (S.E. 11/02/2017)
	T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)	K173125 (S.E. 12/20/2017); K181328 (S.E. 09/19/2018); K183510 (S.E. 01/16/2019)
	These predicate devices have not been subject to a design related recall	
Description of Device	ANATOMIC PEEK™ Cervical Fusion System	The ANATOMIC PEEK Cervical Fusion System consists of cages of various widths and heights which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The ANATOMIC PEEK devices must be used with supplemental fixation.
	ANATOMIC PEEK™ PTC Cervical Fusion Spinal System	The ANATOMIC PEEK™ PTC Cervical Fusion System consists of cages of various widths and heights which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The ANATOMIC PEEK™ PTC devices must be used with supplemental fixation.
	Capstone™ Spinal System	The CAPSTONE™ Spinal System consists of PEEK cages, titanium alloy cages, and titanium cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.**
	Capstone Control™ Spinal System	The CAPSTONE CONTROL™ Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** See the MDT Catalog or price list for further information about warranties and limitations of liability.
	Capstone Control PTC™ Spinal System	The CAPSTONE CONTROL PTC™ Spinal System consists of commercially pure titanium (CP Ti) coated PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.**

	Capstone PTC™ Spinal System	The CAPSTONE PTC™ Spinal System consists of commercially pure titanium (CP Ti) coated PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.**
	Clydesdale™ Spinal System	The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**.
	Clydesdale™ Spinal System (w/Infuse)	The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**, or INFUSE® Bone Graft as designated below.
	Clydesdale PTC™ Spinal System	The CLYDESDALE PTC™ Spinal System consists of commercially pure titanium (CP Ti) coated PEEK cages of various widths and heights, which include tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.**
	Cornerstone™ PSR Cervical Fusion System	The CORNERSTONE® PSR Cervical Fusion System consists of cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** in cervical fusion procedures. The CORNERSTONE® PSR device is to be used with supplemental instrumentation and is to be implanted via an open, anterior approach. See the MDT Catalog or price list for further information about warranties and limitations of liability.
	Crescent™ Spinal System	The CRESCENT® Spinal System consists of PEEK cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The implants may be implanted via a posterior, transforaminal or lateral approach and the procedure may be open or minimally invasive. See the MDT Catalog or

		price list for further information about warranties and limitations of liability.
	Crescent™ Spinal System Titanium	The CRESCENT® Spinal System Titanium consists of implant grade titanium alloy (Ti-6Al-4V) cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The implants may be implanted via a transforaminal or lateral approach and the procedure may be open or minimally invasive.
	Divergence-L™ Anterior/Oblique Lumbar Fusion System	The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System consists of plates, bone screws, and interbody cages. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System plates and bone screws are available in a broad range of size offerings intended for anterior screw fixation and stabilization during the normal healing process following surgical correction of disorders of the spine. Fixation is provided by bone screws inserted into the vertebral body of the lumbar spine using an anterior or oblique approach. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System plate and bone screws are made from titanium alloy and are provided sterile. Additionally, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody cages may be used as supplemental fixation when used in conjunction with posterior fixation devices to treat deformity conditions in the thoracic and lumbar spine. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** or INFUSE™ Bone Graft (as designated below). The cages are manufactured from medical grade polyetheretherketone (PEEK) and titanium alloy with tantalum markers and are provided sterile.

	Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only)	The DIVERGENCE™ Anterior Cervical Fusion System is an intervertebral body fusion device with internal screw fixation. The system is comprised of an interbody cage and bone screws. These implants are for single use only. The DIVERGENCE™ anterior cervical cages are provided in 0 and 6 degrees of lordosis, 5-12mm heights, 15-20mm widths and 12- 16mm depths. This device is intended to be radiolucent, and the interior space of the product is to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The DIVERGENCE™ stand-alone cervical interbody device is manufactured from medical grade polyetheretherketone (PEEK) and contains radiopaque markers made from medical grade titanium alloy. The PEEK interbody cage also comes preassembled with a titanium alloy, built- in rotary locking mechanism. The bone screws used with this device are provided in self-drilling and self-tapping options and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 9-17mm lengths. The PEEK material used conforms to ASTM F2026 and the titanium alloy material used conforms to ASTM F136. To achieve best results, do not use any of the DIVERGENCE™ Anterior Cervical Fusion System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the DIVERGENCE™ Anterior Cervical Fusion System components should ever be reused under any circumstances.
	Elevate™ Spinal System	The ELEVATE™ Spinal System is an expandable PEEK, Tantalum, and Titanium alloy interbody device consisting of various lengths and starting heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The ELEVATE™ Spinal System expands for adjustable lordosis and height to match patient anatomy. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The implants may be implanted via a posterior or transforaminal approach and the procedure may be open or minimally invasive. The ELEVATE™ Spinal System can be implanted unilaterally and bilaterally. The ELEVATE™ Spinal System is intended to be inserted with ELEVATE™ Spinal System reusable instruments. ELEVATE™ Spinal System implants are for single use only.
	Perimeter Interbody Fusion Device	The PERIMETER® Interbody Fusion Device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. The PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation. The device is offered in Titanium Alloy (Titanium- 6Aluminum-4Vanadium ELI) or PEEK (Polyetheretherketone). This interbody device is offered in sterile or non-sterile forms. Refer to the package label for specific implant sterility information. The PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 15mm to 28mm in length, and between 19mm and 38mm in width. An array of lordosis options are

		provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK and Titanium Alloy (Titanium-6Aluminum- 4Vanadium ELI) devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance. Additionally, the Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) version of this device offers lateral windows for visibility of the **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. Medical grade titanium, titanium alloy, and/or medical grade cobalt- chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. PEEK implants may be used with stainless steel, titanium, or cobalt-chromium-molybdenum alloy implants. See the MDT Catalog or price list for further information about warranties and limitations of liability.
	Perimeter Interbody Fusion Device (w/Infuse)	The PERIMETER® Interbody Fusion Device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with either **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** or INFUSE® Bone Graft as designated below. The PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation. The device is offered in Titanium Alloy (Titanium-6Aluminum- 4Vanadium ELI) or PEEK (Polyetheretherketone). However, only the PEEK device is approved for use with INFUSE® Bone Graft. Consult the labeling for the INFUSE® Bone Graft/Medtronic Interbody Fusion Device for approved PEEK PERIMETER® implant sizes. This interbody device is offered in sterile or non- sterile forms. Refer to the package label for specific implant sterility information. The PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 15mm to 28mm in length and between 19mm and 38mm in width. An array of lordosis options are provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK and Titanium Alloy (Titanium-6Aluminum- 4Vanadium ELI) devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance. Additionally, the Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) version of this device offers lateral windows for visibility of the **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.**

	Pivox™ Oblique Lateral Spinal System	The PIVOX™ Oblique Lateral Spinal System consists of interbody cages, plates, and bone screws. The PIVOX™ Oblique Lateral Spinal System interbody cages are available in various widths, heights, and lordosis inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**, or INFUSE™ Bone Graft (as designated below) and must be used with supplemental fixation. The cages are manufactured from medical grade polyetheretherketone (PEEK) and titanium alloy with tantalum markers and are provided sterile. The PIVOX™ Oblique Lateral Spinal System plates and bone screws are available in a broad range of sizes intended for anterior column screw fixation and stabilization during the normal healing process following surgical correction of disorders of the spine. Fixation is provided by bone screws inserted into the vertebral body of the lumbar spine using an anterior, lateral, or oblique approach. The PIVOX™ Oblique Lateral Spinal System plate and bone screws are made from titanium alloy and are provided sterile.
	Sovereign™ Spinal System	The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with 3 holes for placement of titanium screws using an anterior or oblique approach. The SOVEREIGN™ Spinal System contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the polyetheretherketone (PEEK) interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted. The SOVEREIGN™ Spinal System interbody device is manufactured from PEEK (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.
	T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)	The T2 Stratosphere™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self- adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements. T2 Stratosphere™ Expandable Corpectomy System devices for use in the thoracolumbar and cervical spine are restricted to the 13mm diameter centerpieces. The T2 Stratosphere™ Expandable Corpectomy System is made of titanium alloy and is provided sterile and non-sterile. This device is inserted between two vertebral bodies in the thoracolumbar or cervical spine and is expanded to aid in the surgical correction and stabilization of the spine. The centerpieces are available in multiple heights. The system also features modular end caps which are available in various angles and diameters and are only for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

	No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Never use titanium or titanium alloy implants with stainless steel in the same construct.	
Indications for Use:	ANATOMIC PEEK™ Cervical Fusion System	The ANATOMIC PEEK Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK device is to be used with supplemental fixation. The ANATOMIC PEEK Cervical Fusion System is also required to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** and is to be implanted via an open anterior approach.
	ANATOMIC PEEK™ PTC Cervical Fusion Spinal System	The ANATOMIC PEEK PTC Cervical Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at atone disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patent history and radiographic studies. The ANATOMIC PEEK PTC Cervical Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** The ANATOMIC PEEK PTC Cervical Fusion System is to be used with supplemental fication. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.
	Capstone™ Spinal System	The CAPSTONE® Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the CAPSTONE® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the CAPSTONE® Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE® Spinal System is intended to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach.

	Capstone Control™ Spinal System	The Capstone Control™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the Capstone Control™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the Capstone Control™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had 6 months of nonoperative treatment. The Capstone Control™ Spinal System is intended to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach. The 18mm Capstone Control™ Spinal System implant can only be implanted via a Posterior (PLIF) approach. When using the 18mm Capstone Control™ Spinal System implant, a minimum of2 implants are required per spinal level.
	Capstone Control PTC™ Spinal System	The CAPSTONE CONTROL PTC™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the CAPSTONE CONTROL PTC™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the CAPSTONE CONTROL PTC™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE CONTROL PTC™ Spinal System is intended to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach.

	Capstone PTC™ Spinal System	The CAPSTONE PTC™ Spinal System is indicated for interbody fusion in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (FDA) for use in the lumbar spine.
	Clydesdale™ Spinal System	The CLYDESDALE® Spinal System is designed to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.
	Clydesdale™ Spinal System (w/ Infuse)	The CLYDESDALE® Spinal System is intended to be used in interbody fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the CLYDESDALE® Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Certain sizes of the CLYDESDALE® Spinal System may be used with INFUSE® Bone Graft in single-level Oblique Lateral Interbody Fusion (OLIF) procedures from L2 to L5 in patients diagnosed with DDD, as defined above. Consult the labeling for the INFUSE® Bone Graft/Medtronic Interbody Fusion Device for information on the specific sizes of the CLYDESDALE® Spinal System approved for use with INFUSE® Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE® Bone Graft. INFUSE® Bone Graft is not indicated for use in a direct lateral interbody fusion (DLIF) surgical approach. Additionally, the CLYDESDALE® Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. INFUSE® Bone Graft is not indicated for use in patients with this condition. These patients should be skeletally mature and have had six months of nonoperative treatment. The CLYDESDALE® Spinal System is intended

		to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** when the subject device is used as an adjunct to fusion. These implants may be implanted via a minimally invasive lateral approach.
	Clydesdale PTC™ Spinal System	The CLYDESDALE PTC™ Spinal System is designed to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™ Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.
	Cornerstone™ PSR Cervical Fusion System	The CORNERSTONE® PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** and is to be implanted via an open, anterior approach.
	Crescent™ Spinal System	The CRESCENT™ Spinal System is indicated for interbody fusion in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

	Crescent™ Spinal System Titanium	The CRESCENT™ Spinal System Titanium is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.** These devices are intended to be used with Medtronic supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.
	Divergence-L™ Anterior/Oblique Lumbar Fusion System	The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody cage is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 (except as defined for use with INFUSE™ Bone Graft above). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non- operative treatment. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device is intended to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation (L5-S1) of the vascular structures or anterior oblique above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior lumbar spine during the development of spinal fusions in patients with: 1) DDD defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; 2) trauma (including fractures); 3) tumors; 4) deformity defined as kyphosis, lordosis, or scoliosis; 5) pseudarthrosis; and/or 6) failed previous fusions. Certain sizes of the Certain sizes of the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device may also be used with INFUSE™ Bone Graft for patients diagnosed with DDD, as defined above. The device may be implanted at a single level using an Anterior Lumbar Interbody Fusion (ALIF) approach from L2-S1. The device may also be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L5 to S1. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device is intended for use with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine when used to treat DDD. Consult the labeling for the INFUSE™ Bone Graft/Medtronic Interbody Fusion Device for additional information onthe

		specific sizes of the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ Bone Graft. DIVERGENCE-L Anterior/Oblique Lumbar Fusion System interbody device may also be used with INFUSE™ Bone Graft.
	Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only)	The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The DIVERGENCE™ stand-alone cervical interbody device must be used with internal screw fixation. The DIVERGENCE™ stand-alone cervical interbody device is also required to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment. Patients with previous non- fusion spinal surgery at involved level may be treated with the device.
	Elevate™ Spinal System	The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate**. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.
	Perimeter Interbody Fusion Device	The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral, and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

	Perimeter Interbody Fusion Device (w/ Infuse)	The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral, and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine. Certain sizes of the PEEK PERIMETER® Interbody Fusion Device may also be used with INFUSE® Bone Graft for patients diagnosed with DDD, as defined above. The device may be implanted at a single level using an Anterior Lumbar Interbody Fusion (ALIF) approach from L2-S1. The device may also be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L5 to S1. The PEEK PERIMETER® Interbody Fusion Device should be used with supplemental fixation systems cleared for use in the lumbar spine. Consult the labeling for the INFUSE® Bone Graft/Medtronic Interbody Fusion Device for additional information on the specific sizes of the PEEK PERIMETER® Interbody Fusion Device approved for use with INFUSE® Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE® Bone Graft.
	Pivox™ Oblique Lateral Spinal System	The PIVOX™ Oblique Lateral Spinal System Interbody Cage is designed to be used with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The PIVOX™ Oblique Lateral Spinal System interbody cage is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the PIVOX™ Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non- operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach. Certain sizes of the PIVOX™ Oblique Lateral Spinal System Interbody Cage may also be used with INFUSE™ Bone Graft for patients diagnosed with DDD, as defined above, who are skeletally mature and have had six months of non-operative treatment. The device may be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L2- L5 and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Consult the labeling for the INFUSE™ Bone Graft/ Medtronic Interbody Fusion Device for information on the specific sizes of the PIVOX™ Oblique Lateral Spinal System Interbody Cage approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ Bone Graft. INFUSE™ Bone Graft

		is not indicated for use in a direct lateral interbody fusion (DLIF) surgical approach. Additionally, the PIVOX™ Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non- operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach. INFUSE™ Bone Graft is not indicated for use in patients with this condition. The PIVOX™ Oblique Lateral Spinal System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral levels, anterior below the bifurcation (L5-S1) of the vascular structures, and oblique or lateral above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior lumbar spine during the development of spinal fusions in patients with: 1) DDD defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; 2) trauma (including fractures); 3) tumors; 4) deformity defined as kyphosis, lordosis, or scoliosis; 5) pseudarthrosis; and/or 6) failed previous fusions. When used together, the PIVOX™ Oblique Lateral Spinal System components can be used to treat patients with DDD at one or two contiguous levels from L2 to S1 (except as defined for use with INFUSE™ Bone Graft above). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.
	Sovereign™ Spinal System	The SOVEREIGN™ Spinal System is indicated for use with **autogenous bone graft and/or allograft bone graft comprised on cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the SOVEREIGN™ Spinal System is indicated for use in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. The SOVEREIGN™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the SOVEREIGN™ interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).
	T2 Stratosphere™ Expandable Corpectomy System (Cervical and Thoracolumbar)	The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1- L5) and cervical spine (C2-C7). The T2 Stratosphere™ Expandable Corpectomy System is intended for use in skeletally mature patients. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders.

		When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at single or two levels, the T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Corpectomy centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** as an adjunct to fusion. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with **autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate** used at the surgeon's discretion.
Comparison of Technological Characteristics with the Predicate Devices	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. The predicate and subject devices are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The subject devices were originally cleared for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft. **The subject application provides published clinical outcomes to support the use of demineralized allograft bone with bone marrow aspirate.**	
Performance Data	No performance testing was required or performed, as this modification for this Special 510(k) relates only to the indications for use. **Biocompatibility** No new implants or instruments were included in this submission. **Mechanical Testing** No new mechanical testing was performed or required to support this application. **Design Validation** No new Design Validation testing was required as this submission does not include any new or modified instruments or implants. A minor change was included in the surgical technique, but this only involves the inclusion of demineralized allograft bone mixed with bone marrow aspirate and does not impact implant or instrument design. **Clinical Outcomes** Clinical outcomes on the usage of demineralized allograft bone combined with bone marrow aspirate were provided to support this application.	

Conclusion	Based upon the supporting documentation provided in the pre-market notification, the subject devices are safe and effective as the primary predicates ARTiC-L™ 3D Ti Spinal System and the ARTiC- XL™ 3D Ti Spinal System found in K190959 and Endoskeleton TA Interbody Fusion Device, Endoskeleton TAS and TAS Hyperlordotic 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 – K192018, when demineralized allograft bone combined with bone marrow aspirate is used.

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)*
Unknown

Device Name
ANATOMIC PEEK™ Cervical Fusion System

Indications for Use *(Describe)*
The ANATOMIC PEEK Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK device is to be used with supplemental fixation. The ANATOMIC PEEK Cervical Fusion System is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate and is to be implanted via an open anterior approach.

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.

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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)*
Unknown

Device Name
ANATOMIC PEEK™ PTC Cervical Fusion System

Indications for Use *(Describe)*
The ANATOMIC PEEK PTC Cervical Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at atone disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patent history and radiographic studies. The ANATOMIC PEEK PTC Cervical Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. The ANATOMIC PEEK PTC Cervical Fusion System is to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

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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Indications for Use

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

Device Name
Capstone™ Spinal System

Indications for Use *(Describe)*
The CAPSTONE™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the discconfirmed by history and radiographic studies. When used for these indications, the CAPSTONE™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the CAPSTONE™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE™ Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/ or transforaminal approach.

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)*
Unknown

Device Name
Capstone Control™ Spinal System

Indications for Use *(Describe)*
The Capstone Control™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 contiguous levels from L2 to S1. DDD patients may also have up to Grade 1spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the Capstone Control™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the Capstone Control™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had 6 months of nonoperative treatment. The Capstone Control™ Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach. The 18mm Capstone Control™ Spinal System implant can only be implanted via a Posterior (PLIF) approach. When using the18mm Capstone Control™ Spinal System implant, a minimum of 2 implants are required per spinal level.

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)*
Unknown

Device Name
Capstone Control PTC™ Spinal System

Indications for Use *(Describe)*
The CAPSTONE CONTROL PTC™ Spinal System is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the CAPSTONE CONTROL PTC™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the CAPSTONE CONTROL PTC™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. The CAPSTONE CONTROL PTC™ Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach.

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)*
Unknown

Device Name
Capstone PTC™ Spinal System

Indications for Use *(Describe)*
The CAPSTONE PTC™ Spinal System is indicated for interbody fusion in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (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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Indications for Use

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

Device Name
Clydesdale™ Spinal System

Indications for Use *(Describe)*

The CLYDESDALE™ Spinal System is intended to be used in interbody fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the CLYDESDALE™ Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Certain sizes of the CLYDESDALE™ Spinal System may be used with INFUSE™ Bone Graft in single-level Oblique Lateral Interbody Fusion (OLIF) procedures from L2 to L5 in patients diagnosed with DDD, as defined above. Consult the labeling for the INFUSE™ Bone Graft/Medtronic Interbody Fusion Device for information on the specific sizes of the CLYDESDALE™ Spinal System approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ Bone Graft. INFUSE™ Bone Graft is not indicated for use in a direct lateral interbody fusion (DLIF) surgical approach. Additionally, the CLYDESDALE™ Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. INFUSE™ Bone Graft is not indicated for use in patients with this condition. These patients should be skeletally mature and have had six months of nonoperative treatment. The CLYDESDALE™ Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device is used as an adjunct to fusion. These implants may be implanted via a minimally invasive lateral approach.

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)*
Unknown

Device Name
Clydesdale PTC™ Spinal System

Indications for Use *(Describe)*
The CLYDESDALE PTC™ Spinal System is designed to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants maybe implanted via a minimally invasive lateral approach.

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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Indications for Use

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

Device Name
Cornerstone™ PSR Cervical Fusion System

Indications for Use *(Describe)*
The CORNERSTONE™ PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE™ PSR device is to be used with supplemental fixation. The CORNERSTONE™ PSR device is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate and is to be implanted via an open, anterior approach.

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)*
Unknown

Device Name
Crescent™ Spinal System

Indications for Use *(Describe)*
The CRESCENT™ Spinal System is indicated for interbody fusion in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These devices are intended to be used with supplemental fixation instrumentation which 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)

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

Device Name
Crescent™ Spinal System Titanium

Indications for Use *(Describe)*
The CRESCENT™ Spinal System Titanium is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These devices are intended to be used with Medtronic supplemental fixation instrumentation which 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)

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

Device Name
Divergence-L™ Anterior/Oblique Lumbar Fusion System

Indications for Use *(Describe)*
The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody cage is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 (except as defined for use with INFUSE™ Bone Graft above). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non-operative treatment. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. The DIVERGENCE-L™ Anterior/ Oblique Lumbar Fusion System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation (L5-S1) of the vascular structures or anterior oblique above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior lumbar spine during the development of spinal fusions in patients with: 1) DDD defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; 2) trauma (including fractures); 3) tumors; 4) deformity defined as kyphosis, lordosis, or scoliosis; 5) pseudarthrosis; and/or 6) failed previous fusions. Certain sizes of the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device may also be used with INFUSE™ Bone Graft for patients diagnosed with DDD, as defined above. The device may be implanted at a single level using an Anterior Lumbar Interbody Fusion (ALIF) approach from L2-S1. The device may also be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L5 to S1. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device is intended for use with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine when used to treat DDD. Consult the labeling for the INFUSE™ Bone Graft/Medtronic Interbody Fusion Device for additional information on the specific sizes of the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ 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)

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

Device Name
Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only)

Indications for Use *(Describe)*
The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/orosteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The DIVERGENCE™ stand-alone cervical interbody device must be used with internal screw fixation. The DIVERGENCE™ stand-alone cervical interbody device is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device."

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)*
Unknown

Device Name
Elevate™ Spinal System

Indications for Use *(Describe)*
The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These devices are intended to be used with supplemental fixation instrumentation, which 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)

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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)*
Unknown

Device Name
Perimeter™ Interbody Fusion Device

Indications for Use *(Describe)*
The PERIMETER™ Interbody Fusion Device is indicated for interbody fusion with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral, and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine. Certain sizes of the PEEK PERIMETER™ Interbody Fusion Device may also be used with INFUSE™ Bone Graft for patients diagnosed with DDD, as defined above. The device may be implanted at a single level using an Anterior Lumbar Interbody Fusion (ALIF) approach from L2-S1. The device may also be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L5 to S1. The PEEK PERIMETER™ Interbody Fusion Device should be used with supplemental fixation systems cleared for use in the lumbar spine. Consult the labeling for the INFUSE™ Bone Graft/Medtronic Interbody Fusion Device for additional information on the specific sizes of the PEEK PERIMETER™ Interbody Fusion Device approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ 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)

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

Device Name
Pivox™ Oblique Lateral Spinal System

Indications for Use *(Describe)*

The PIVOX™ Oblique Lateral Spinal System Interbody Cage is designed to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The PIVOX™ Oblique Lateral Spinal System interbody cage is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the PIVOX™ Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non- operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach. Certain sizes of the PIVOX™ Oblique Lateral Spinal System Interbody Cage may also be used with INFUSE™ Bone Graft for patients diagnosed with DDD, as defined above, who are skeletally mature and have had six months of non-operative treatment. The device may be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L2- L5 and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Consult the labeling for the INFUSE™ Bone Graft/Medtronic Interbody Fusion Device for information on the specific sizes of the PIVOX™ Oblique Lateral Spinal System Interbody Cage approved for use with INFUSE™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with INFUSE™ Bone Graft. INFUSE™ Bone Graft is not indicated for use in a direct lateral interbody fusion (DLIF) surgical approach. Additionally, the PIVOX™ Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation.These patients should be skeletally mature and have had six months of non- operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach. INFUSE™ Bone Graft is not indicated for use in patients with this condition. The PIVOX™ Oblique Lateral Spinal System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral levels, anterior below the bifurcation (L5-S1) of the vascular structures, and oblique or lateral above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior lumbar spine during the development of spinal fusions in patients with: 1) DDD defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; 2) trauma (including fractures); 3) tumors; 4) deformity defined as kyphosis, lordosis, or scoliosis; 5) pseudarthrosis; and/or 6) failed previous fusions. When used together, the PIVOX™ Oblique Lateral Spinal System components can be used to treat patients with DDD at one or two contiguous levels from L2 to S1 (except as defined for use with INFUSE™ Bone Graft above). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

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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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K192502

Device Name
Sovereign™ Spinal System

Indications for Use *(Describe)*
The Sovereign™ Spinal System is indicated for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the Sovereign™ Spinal System is indicated for use in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ Spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ Spinal System is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

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)*

Device Name
T2 Stratosphere(TM) Expandable Corpectomy System (Cervical and Thoracolumbar)

Indications for Use *(Describe)*
The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) and cervical spine (C2-C7). The T2 Stratosphere™ Expandable Corpectomy System is intended for use in skeletally mature patients.
When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at single or two levels, the T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine.
When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Corpectomy centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate used at the surgeon's discretion.

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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