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

July 3, 2019

Re: K190959
Trade/Device Name: ARTiC-L™ 3D Ti Spinal System with TiONIC™ Technology, ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 11, 2019
Received: June 13, 2019

Dear Emmarie 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,

for Melissa Hall
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190959

Device Name
ARTiC-L™ 3D Ti Spinal System with TiONIC ™ Technology and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology

Indications for Use *(Describe)*
The ARTiC-L™ 3D Ti Spinal System with TiONIC™ technology is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DOD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the ARTiC-L™ 3D Ti Spinal System with TiONIC™ technology can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine 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. When used as an interbody fusion device, these implants are intended for use with supplemental internal fixation systems.

The ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DOD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the ARTiC-XL™ 3D Ti Spinal System with TiONIC TM technology can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine 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.

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.

510(k) Summary
Medtronic Sofamor Danek
ARTiC-L™ 3D Ti and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology
April 2019

Submitter	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact(s)	Emmarie Halteman Associate Regulatory Affairs Specialist Direct Telephone – 901-399-2216
Date Prepared	April 10th, 2019
Common Name	ARTiC-L™ 3D Ti Spinal System with TiONIC™ Technology ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology
Regulatory Class **Regulation Number** **Regulation Name** **Device Product Classification Code**	Class II 888.3030 Intervertebral Body Fusion Device with Bone Graft MAX
Predicate Devices	K171689 ARTiC-L™ 3D and ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology (SE 10/05/17) These predicate devices have not been subject to a design related recall
Description of Device	The ARTiC-L™ 3D Ti Spinal System with TiONIC™ technology consists of additive manufactured titanium cages of various widths, lengths, heights, and lordotic angles to accommodate patient anatomy. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The articulating device assembly allows for placement of implant while remaining attached to inserter. The open geometry of the implants allows them to be packed with autograft bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone (e.g., minimally manipulated allograft such as Grafton™ DBM DBF, etc.) Demineralized bone must be used with bone marrow aspirate. The device is not intended to be used as a stand-alone implant. Stainless steel and titanium implants are not compatible. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.
Indications for Use:	The ARTiC-L™ 3D Ti Spinal System with TiONIC™ technology is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the ARTiC-L™ 3D Ti Spinal System with TiONIC™ technology can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine 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. When used as an interbody fusion device, these implants are intended for use with supplemental internal fixation systems. The ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ technology can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine 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.
Comparison of Technological Characteristics with the Predicate Devices	ARTiC-L™ 3D Ti and ARTiC-XL™ 3D Ti Spinal System devices have the same fundamental scientific technology; indications for use, intended use, design, material levels of attachment as the 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. Both the ARTiC-L™ 3D Ti and ARTiC-XL™ 3D Ti Spinal System devices were originally cleared for use with autogenous bone and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. The subject application provides published clinical outcomes to support the use of demineralized allograft bone with bone marrow aspirate.
Performance Data	**MRI Safety Evaluation** MRI Safety Evaluation was previously completed in accordance with: • **ASTM F2052:2015:** *Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment* • **ASTM F2213:2006 (R11):** *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment* • **ASTM F2119:2007(R13)**: *Standard test method for evaluation of MR image artifacts from passive implants* • **ASTM F2182:2002a, 2011, 2011a**: *Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging* **Design Validation** 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 ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System are safe and effective as the predicate ARTiC-L™ 3D Ti Spinal System and the ARTiC-XL™ 3D Ti Spinal System found in K171689, when demineralized allograft bone combined with bone marrow aspirate is used.