Medtronic Sofamor Danek, USA Inc.
Mr. Tejas Patel
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

October 5, 2017

Re: K171689
Trade/Device Name: ARTiC-L™ 3D Ti Spinal System with TiONIC Technology and 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: September 1, 2017
Received: September 5, 2017

Dear Mr. Patel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171689

Device Name
ARTiC-L™ 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 (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, ARTiC-L™ 3D Ti Spinal System 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 allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. When used as an interbody fusion device, these implants are intended for use with supplemental internal fixation systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171689

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

Indications for Use *(Describe)*

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, ARTiC-XL™ 3D Ti Spinal System 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 allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. When used as an interbody fusion device, these implants are intended for use with supplemental internal fixation systems.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek
ARTiC-L™ 3D Ti Spinal System
ARTiC-XL™ 3D Ti Spinal System
with TiONIC ™ Technology

September 28, 2017

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Tejas Patel Sr. Regulatory Affairs Specialist Telephone: (901) 344-1443 (Direct)
Alternate Contact:	Raphael McInnis Regulatory Affairs Manager Telephone: (901) 399-2057 (Direct)
Date Prepared	September 28, 2017
Name of Device	ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology
Common Name	Interbody fusion device
Classification Name	Intervertebral Body Fusion Device with bone graft (21 CFR 888.3080)
Regulatory Class	Class II
Product Code	MAX
Predicate Devices	Predicate 1 (Primary) – DePuy Synthes T-PAL Spacer System K162358 SE 11/01/2016 Predicate 2 CRESCENT® Ti K122037 SE 03/22/2013 Predicate 3 K2M CASCADIA™ TL Interbody System K160547 SE 03/24/2016 Predicate 4 NuVasive® Brigade® Hyperlordotic System K123045 SE 04/16/2013 Predicate 5 CLYDESDALE® Spinal System K151128 SE 08/06/2015 Predicate 6 WAVE-D Spinal System K121333 SE 06/29/2012 Predicate 7 CAPSTONE® PEEK K073291 SE 04/24/2008, K123027 SE 07/25/2013 Predicate 8 CAPSTONE® PTC K133205 SE 03/13/2014 Predicate 9 CRESCENT® Spinal System

	K094025 SE 04/26/2010 Predicate 10 LOOP® Spinal System K121332 SE 06/29/2012
Description of Device	The ARTiC-L™ and ARTiC-XL™ 3D Ti Spinal Systems with TiONIC™ Technology consist of additively manufactured (AM) titanium spacers of various widths, lengths, heights and lordotic angles and reusable instruments used for implantation and extraction of the subject implant. The instruments may be transported to the customer in cases, trays and lids which can also be used for sterilization. These implants are intended to be surgically placed between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion surgical procedures.
Indications for Use	**ARTiC-L™ 3D Ti Spinal System with TiONIC™ Technology** 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, ARTiC-L™ 3D Ti Spinal System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems. **ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology** 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, 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 six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion

	in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems.
Comparison of Technological Characteristics with the Predicate Devices:	ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System with TiONIC ™ Technology has 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.
Performance Data:	The following performance data were provided in support of substantial equivalence. **Biocompatibility** The biocompatibility evaluation for the ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System implants was conducted in accordance with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016. The subject implants are temporary implants and will be classified as permanent, >30-day body contact according to with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016. The subject implants are manufactured from Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy. The following tests have been conducted to ensure biocompatibility: • Chemical Characterization • Toxicological Risk Assessment • Cytotoxicity • Acute Systemic Toxicity

- Material Mediated Pyrogenicity

Based on the results, no additional testing was required.

The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in **ANSI/AAMI ST72**: *Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.*

The subject instruments are external communicating devices and are classified as limited, up to 24 hours of body contact according to with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016. The instruments are manufactured from Stainless Steel, in accordance with ASTM F899, ASTM A564 and ASTM A693 and Titanium Alloy ELI, in accordance with F136. The subject instruments are provided non-sterile and are intended for steam sterilization by the end user prior to use. The subject instruments can be packaged and shipped in case, trays and lids, the subject instruments can be steam sterilized in these case, trays, and lids.

- **ASTM F899** *Standard Specification for Wrought Stainless Steels for Surgical Instruments*
- **ASTM A564** *Standard Specification for Hot Rolled and Cold Finished Age Hardening Stainless Steel Bars and Shapes*
- **ASTM A693** *Standard Specification for Precipitation-Hardening Stainless and Heat Resisting Steel Plate, Sheet and Strip*
- **ASTM F136:** *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

The system specific tray used for shipment and sterilization of instruments is

manufactured from stainless steel, aluminum, nylon coated stainless steel, radel, polypropylene with the brackets securing the instruments into the case/tray made of silicone and/or nylon coated stainless steel and/or polypropylene. These materials are non-patient contacting and indirect patient contacting and are the same materials as the predicate. Therefore, no new biocompatibility testing is required.

Mechanical Testing

In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. A combination of engineering rationales and testing were used to establish substantial equivalence. The following bench testing was completed and the results of these tests demonstrated the substantial equivalence of the subject devices to the predicates.

Performance testing was completed in accordance with:

- **ASTM F2077-14** *Test Methods for Intervertebral Body Fusion Devices*

  Following mechanical tests were performed per ASTM F2077-14:
  - Static Compression Testing
  - Static Compression-Shear Testing
  - Compression Fatigue Testing
  - Compression-Shear Fatigue Testing

- **ASTM F2267-04 (2011)** *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*

- **ASTM Draft Standard F-04.25.02.02**: *Static Push-out Test Method for Intervertebral Body Fusion Devices*

- **ASTM F1877-16:** *Standard Practice for Characterization of Particle*

MRI Safety Evaluation was 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** Design Validation was performed using saw bone models and/or cadaver lab (Tru-Trainer) for the subject ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System implants and instruments. Design Validation demonstrated the subject implants and instruments function as intended and user needs were met.
Conclusion:	Based on the test results and additional supporting documentation provided in the pre-market notification, the subject ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System are as safe and effective as the following predicates: Predicate 1 (Primary) – DePuy Synthes T-PAL Spacer System K162358 SE 11/01/2016 Predicate 2 CRESCENT® Ti K122037 SE 03/22/2013 Predicate 3 K2M CASCADIA™ TL Interbody System K160547 SE 03/24/2016 Predicate 4 NuVasive® Brigade® Hyperlordotic System K123045 SE 04/16/2013 Predicate 5 CLYDESDALE® Spinal System K151128 SE 08/06/2015 Predicate 6 WAVE-D Spinal System K121333 SE 06/29/2012 Predicate 7 CAPSTONE® PEEK K073291 SE 04/24/2008, K123027 SE 07/25/2013 Predicate 8 CAPSTONE® PTC K133205 SE 03/13/2014 Predicate 9 CRESCENT® Spinal System K094025 SE 04/26/2010 Predicate 10 LOOP® Spinal System K121332 SE 06/29/2012