December 20, 2019

Pioneer Surgical Technology, Inc., DBA RTI Surgical, Inc.
Ms. Linda Busklein
Principal Specialist, Regulatory Affairs
375 River Park Circle
Marquette, Michigan 49855-0627

Re: K192718
Trade/Device Name: Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: November 27, 2019
Received: November 29, 2019

Dear Ms. Busklein:

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 L. Showalter, PhD
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)*
K192718

Device Name
Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology

Indications for Use *(Describe)*

When the Fortilink-A is used as a lumbar interbody fusion (IBF) implant, it is indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This IBF device is used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF device is intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of non-operative treatment prior to treatment with an interbody fusion device. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

When Fortilink-C is used as cervical interbody fusion (IBF) implants, these devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the cervical spine and are placed via an anterior approach from C2-C3 to C7-T1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device.

When Fortilink-TS and Fortilink-L are used as lumbar interbody fusion (IBF) implants, these devices are indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of non-operative treatment prior to treatment with an interbody fusion 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)

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."

510(k) Summary

Device Trade Name:	Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology, including the following designs: - Fortilink®-C IBF System - Fortilink®-TS IBF System - Fortilink®-L IBF System - Fortilink®-A IBF System
Manufacturer:	Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA Registration no: 1833824
Contact:	Linda Busklein, Principal Specialist, Regulatory Affairs Telephone: (855) 455-1061
Date Prepared:	September 26, 2019
Common Name:	Intervertebral Body Fusion Device (IBF)
Classification Regulation:	21 CFR 888.3080 Intervertebral body fusion device
Class	II
Product Codes:	ODP (Intervertebral fusion device with bone graft, cervical) MAX (Intervertebral fusion device with bone graft, lumbar)

Predicate Devices:

Primary - Fortilink®-L Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology (K190498)

Additional - Fortilink®-C Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology (K163673)

Purpose

The purpose of this submission is to obtain clearance for the Fortilink®-A Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology, an additional design of the family of Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology (Fortilink). In addition, this submission seeks clearance of MR Conditional labeling information for all devices of the Fortilink family. There have been no other changes to the Fortilink devices, including no change in design, materials, sterilization, or processing.

Device Description:

The Fortilink® interbody fusion (IBF) devices are designed to be inserted into the intervertebral body space of the spine and are intended for intervertebral body fusion. These implants are manufactured from a radiolucent polymer (PolyEtherKetoneKetone (PEKK)) (ASTM F2820) which should support radiographic imaging inside the implant to evaluate fusion status and are assembled with radiographic markers composed of tantalum (ASTM F560) to facilitate proper implant position. The implant is provided sterile by gamma irradiation and is intended to be used with supplemental fixation cleared for the implanted level. The implant is supplied with instrumentation necessary to facilitate the insertion and removal of the implant, as well as general manual surgical instruments.

The implant is provided in different footprints and varying heights to provide implant options best suited to an individual's pathology and anatomical condition.

Indications for Use:

When the Fortilink-A is used as a lumbar interbody fusion (IBF) implant, it is indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This IBF device is used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF device is intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of non-operative treatment prior to treatment with an interbody fusion device. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

When Fortilink-C is used as cervical interbody fusion (IBF) implants, these devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the cervical spine and are placed via an anterior approach from C2-C3 to C7-T1 using autogenous bone graft and/ or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device.

When Fortilink-TS and Fortilink-L are used as lumbar interbody fusion (IBF) implants, these devices are indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of non-operative treatment prior to treatment with an interbody fusion device.

Technological Characteristics:

The subject of this 510(k) is the addition of the Fortilink-A design to the Fortilink family of interbody fusion (IBF) devices. The Fortilink-A has the same intended use and technological characteristics as the predicate devices, including design, principles of operation, materials, packaging, and processes including sterilization. The addition of the Fortilink-A adds additional sizes, footprints, and lordosis to the existing family of devices. Reusable insertion instruments are provided with the IBF implants. Performance testing and engineering rationales have demonstrated that the additional sizes, footprints, and lordosis do not raise different issues of safety and effectiveness than the predicate devices.

Non-Clinical Performance Testing:

Mechanical Testing:

The subject Fortilink-A was assessed against the worst-case construct for the predicate family of Fortilink devices. The worst-case construct was tested for the following attributes:

- Static and dynamic torsion testing
- Static and dynamic axial compression
- Subsidence
- Expulsion

In conformance with the standard test methods listed below:

- ASTM F2077-18, Test Methods for Intervertebral Body Fusion Devices
  - Static and Dynamic Axial Compression testing
  - Static and Dynamic Torsion testing
- DRAFT Z8423Z, Static Push-Out Test Method for Intervertebral Body Fusion Devices, Submitted to ASTM F-04.25.02.02
  - Expulsion testing
- ASTM F2267-04 (2018), Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
  - Subsidence testing

The associated device inserter instruments share the same principles of operation, design, materials, and manufacturing processes as the predicate devices. Evaluation of the inserters for insertion/removal and reusability testing demonstrated that the inserters do not present different issues of safety and effectiveness than the predicates.

MR Safety testing

The Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology family of devices are MR Conditional as determined by testing to the following standards and guidance documents:

- ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-11a Standard Test Method for Measurement for Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119-07 (Reapproved 2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- Guidance for Industry and Food and Drug Administration Staff, Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices

Conclusion

Base on the information provided above, the Fortilink®-A Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology is substantially equivalent to the predicate devices. The Fortilink® Interbody Fusion Device (IBF) with TETRAfuse® 3D Technology family of devices are MR Conditional.