Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. July 5, 2019
% Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K190498
Trade/Device Name: Fortilink® IBF System with TETRAfuse®3D Technology, include the following designs: Fortilink®-TS IBF System, Fortilink®-L IBF System, Fortilink®-C IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: June 4, 2019
Received: June 4, 2019

Dear Justin Eggleton:

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)*
K190498

Device Name
Fortilink® IBF System with TETRAfuse®3D Technology, include the following designs: Fortilink®-TS IBF System, Fortilink®-L IBF System, Fortilink®-C IBF System

Indications for Use *(Describe)*

Cervical Interbody Fusion

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.

Lumbar Interbody Fusion

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.

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510(K) SUMMARY

Device Trade Name: Fortilink® IBF System with TETRAfuse®3D Technology, include the following designs:
-Fortilink®-C IBF System
-Fortilink®-TS IBF System
-Fortilink®-L IBF System

Manufacturer: Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.
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Registration no: 1833824

Contact: Kristina Hall, Sr. Manager, Regulatory Affairs
Telephone: 386.418.8888

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Date Prepared: February 28, 2019

Classifications: 21 CFR §888.3080

Class: II

Product Codes: ODP (Intervertebral fusion device with bone graft, cervical)
MAX (Intervertebral fusion device with bone graft, lumbar)

Indications for Use:
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.

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. The purpose of this 510(k) is to seek marketing clearance for modifications to the straight and angled inserter tools for the Fortilink®-L device. The modifications include the following:

Straight Inserter: Improve opening mechanism and disassembly prevention features

Angled Inserter:

- Apply an offset and angle to the inserter handle to align it with the Fortilink®-L implant
- Apply the same design changes (improved opening mechanism and disassembly features) as applied for the straight inserter

Primary Predicate Device:
The Fortilink® IBF System with TETRAfuse®3D Technology with modified inserter tools is substantially equivalent to the primary predicate device of the same name (K172343) with respect to indications, design, material, function, and performance.

Substantial Equivalence:
Engineering analysis and testing included risk analysis, simulated insertion/removal testing, tissue blocking opening testing, reuse testing, and stack-up of design drawings. All completed tests met the pre-determined acceptance criteria.

Conclusion:
Based on the information provided above, the Fortilink® IBF System with TETRAfuse®3D Technology with modified inserter tools is substantially equivalent to the cited primary predicate.