RTI Surgical, Inc.
Diana Taylor
Sr. Regulatory Specialist
375 River Park Circle
Marquette, MI 49855

October 23, 2017

Re: K172343
Trade/Device Name: Fortilink® Interbody Fusion (IBF) System 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: September 28, 2017
Received: September 29, 2017

Dear Ms. Taylor:

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,

Mark N. Melkerson -S

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)*
K172343

Device Name

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

Indications for Use *(Describe)*

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.

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510(k) Summary Pursuant to 21 CFR 807.92

Sponsor: RTI Surgical, Inc.
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Fax: (386) 418-1627

Prepared: October 20, 2017

Trade name: Fortilink® Interbody Fusion (IBF) System with TETRAfuse® 3D Technology

Common name: Intervertebral Body Fusion Implants

Regulation: 21 CFR 888.3080; Class II

Product Codes: MAX and ODP

Device Panel: Orthopedic

Predicate Devices: Primary Predicate Device: K170643 PEEK IBF/VBR System
Reference Device: K163673, Fortilink®-C with TETRAfuse® 3D Technology

Description: The 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 implants are provided sterile by gamma irradiation and are intended to be used with supplemental fixation cleared for the implanted level. The implants are supplied with instrumentation necessary to facilitate the insertion and removal of the implants, as well as general manual surgical instruments.

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

The following designs are included in the Fortilink IBF System :

- Fortilink-C IBF System
- Fortilink-TS IBF System
- Fortilink-L IBF System

Pre-Clinical Performance Data:	The following Fortilink IBF System worst case construct pre-clinical performance data supports the determination of substantial equivalence: • ASTM F2077, Test Methods for Intervertebral Body Fusion Devices, for static and dynamic axial compression and static and dynamic torsion. • ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression, for static subsidence. • DRAFT Z8423Z, Static Push-Out Test Method for Intervertebral Body Fusion Devices, for static expulsion/push-out. Pyrogenicity of the sterile devices was evaluated using the Limulus Amebocyte Lysate (LAL) assay. The devices are tested to ensure the endotoxin level meets the requirements of maximum endotoxin limit for implantable medical devices [20 EU per device].
Indication 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
Conclusion	This submission supports that the subject Fortilink IBF devices are substantially equivalent to the previously cleared predicate devices. The subject and predicate devices are equivalent in terms of indications for use, sterilization, packaging, technological characteristics, design features, and mechanical strength. There are no significant differences between the subject and predicate devices that would impact the safety and effectiveness of the Fortilink IBF system.