DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2017

RTI Surgical, Inc. dba RTI Biologics
Jennifer Bonacci
Regulatory Affairs Specialist
11621 Research Circle
Alachua, Florida 32615

Re: K170643
Trade/Device Name: Interbody Fusion (IBF)/Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: February 28, 2017
Received: March 2, 2017

Dear Ms. Bonacci:

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 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170643

Device Name
lnterbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*

CERVICAL INTERBODY FUSION DEVICE

When used as a cervical intervertebral body fusion implant, the Interbody Fusion (IBF)/ Vertebral Body Replacement (VBR) System ("IBF/VBR System") is indicated for intervertebral body fusion of the spine in skeletally mature patients. Cervical IBFs are intended for use at one level in the cervical spine, from the C2 to C3 intervertebral body space to the C7 to T1 intervertebral body space, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Cervical IBFs are to be used in patients who have had six weeks of non-operative treatment. IBFs are designed for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level.

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.

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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:

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Food and Drug Administration
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Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K170643

Device Name
lnterbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*
LUMBAR INTERBODY FUSION DEVICE
When used as a lumbar intervertebral body fusion implant, the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System ("IBF/VBR System") is indicated for intervertebral body fusion of the spine in skeletally mature patients. Lumbar IBFs are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1 intervertebral body space, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Lumbar IBFs are to be used in patients who have had six months of non-operative treatment. IBFs are designed for use with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level.

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)

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510(k) Number *(if known)*
K170643

Device Name
lnterbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*

VERTEBRAL BODY REPLACEMENT

When used as a vertebral body replacement (VBR) implant, the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System ("IBF/VBR System") is intended for use in the thoracolumbar spine, from T1 to L5, for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. VBRs are also indicated for treating fractures of the thoracic and lumbar spine. VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system is intended to be used with supplemental fixation cleared for the conditions listed above (i.e., tumor or trauma of T1 to L5). Additionally, the VBR implant is intended to be used with bone graft.

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 Pursuant to 21 CFR 807.92

Sponsor:	Pioneer Surgical Technology, Inc. dba RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA Contact: Jennifer Bonacci, Regulatory Affairs Specialist Kristina Hall, Sr. Manager, Regulatory Affairs Ph: (386) 418-8888 Fax: (386) 418-418-1627 Prepared: April 13, 2017
Name:	Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System
Trade names:	C-Plus, Rotate, Bullet-Tip, T-Plus, Contact, Cross-Fuse, Cross-Fuse II, Cross-Fuse II Coronal Taper, Cross-Fuse II Hyperlordotic
Common name:	Intervertebral Body Fusion Device/ Vertebral Body Replacement Device
Classifications:	21 CFR 888.3080 – Class II 21 CFR 888.3060 – Class II
Product Codes:	MAX, ODP, MQP
Panel/ Branch:	Orthopedic and Rehabilitation Devices Panel; Panel Code 87 Restorative Devices Branch
Primary Predicate Device	Pioneer IBF/VBR System K150521
Additional Predicate Devices:	Pioneer IBF/VBR System (K043206, K061151, K073177, K112496, K133623, K133455, and K150521) Rampart™ O, Rampart™ T and Rampart™ A Lumbar Interbody Fusion Device (K160906)
Description:	The system includes implantable devices manufactured from PEEK with tantalum or titanium alloy radiographic markers that are available in a variety of different shapes and sizes to accommodate varying patient anatomy and surgical approach. The IBF/VBR implants may be implanted via a variety or open or minimally invasive approaches, including anterior, lateral, posterior and oblique. Implant-specific and 510(k) exempt orthopedic manual surgical

instruments, including the Clarity Retractor System, are also available for use with the system.

Purpose of Submission:

The purpose of this submission is to expand the lumbar interbody fusion device indications to include the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft for use with K150521 predicate devices. Also, removal of referenced supplemental spinal fixation trade names from the indications statement. Additional administrative changes to the package insert were also included. No changes to the devices were subject to this submission.

Intended Use / Indications for Use:

CERVICAL INTERBODY FUSION DEVICE

When used as a cervical intervertebral body fusion implant the Interbody Fusion (IBF)/ Vertebral Body Replacement (VBR) System ("IBF/VBR System") is indicated for intervertebral body fusion of the spine in skeletally mature patients. Cervical IBFs are intended for use at one level in the cervical spine, from the C2 to C3 intervertebral body space to the C7 to T1 intervertebral body space, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Cervical IBFs are to be used in patients who have had six weeks of non-operative treatment. IBFs are designed for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level.

LUMBAR INTERBODY FUSION DEVICE

When used as a lumbar intervertebral body fusion implant the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System ("IBF/VBR System") is indicated for intervertebral body fusion of the spine in skeletally mature patients. Lumbar IBFs are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1 intervertebral body space, for the treatment of degenerative disc disease (DDD) with up to Grade One spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Lumbar IBFs are to be used in patients who have had six months of non-operative treatment. IBFs are designed for use with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level.

VERTEBRAL BODY REPLACEMENT

When used as a vertebral body replacement (VBR) implant the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System ("IBF/VBR System") is intended for use in the thoracolumbar spine, from T1 to L5 intervertebral body space for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. VBRs are also indicated for treating fractures of the thoracic and lumbar spine. VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system is intended to be used with supplemental fixation cleared for the conditions listed above (i.e., tumor or trauma of T1 to L5 intervertebral body space). Additionally, the VBR implant is intended to be used with bone graft.

Summary of Technological Characteristics:

The technological characteristics remain unchanged since K150521. As stated above, the purpose of this 510(k) submission is to modify the K150521 indications for use statement only; the subject system is equivalent in terms of design, materials, surgical approaches, sterilization and packaging as compared to K150521.

Performance Data Supporting Substantial Equivalence Determination:

No new performance data was provided to support substantial equivalence. Instead, a literature analysis of published clinical data for the lumbar interbody fusion devices similar to the predicate device Rotate, Bullet-Tip, T-Plus, Contact, Cross-Fuse, and Cross-Fuse II (K150521) was provided in support of the expanded Indications for Use. The published clinical outcomes demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, in lumbar interbody fusion procedures to treat patients diagnosed with lumbar disc disease, as defined, poses no new risks to patients. Performance data was also not required in the removal of the spinal fixation system trade names, as this is only an administrative change.

No changes were made to the existing devices, nor were any new components added to the system. There were no changes to the sterilization, shelf life and packaging as presented in K150521. However, pyorgenicity evaluation of the sterile implants has been added based on recent Agency guidance. Pyrogenicity of the device was evaluated using the Limulus Amoebocyte Lysate (LAL) assay on the final sterilized device. The device did not elicit a response. All device lots will be tested to ensure the endotoxin level is 20 EU/device.

Conclusion: The subject indications for use changes to the predicate K150521 system does not raise new issues of safety or effectiveness. The device itself remains unchanged and will perform as safe and as effective as previously cleared. A literature analysis was performed and no new performance data was required to support substantial equivalence.