



Food and Drug Administration
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RTI Surgical, Incorporated dba RTI Biologics
Ms. Jennifer Bonacci
Regulatory Affairs specialist
11621 Research Circle
Alachua, Florida 32615

May 15, 2015

Re: K150521

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: ODP, MAX, MQP
Dated: February 27, 2015
Received: March 2, 2015

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" (21CFR 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 yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K150521

Device Name

Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

Indications for Use (Describe)

CERVICAL INTERBODY FUSION DEVICE

When used as a cervical intervertebral body fusion device (C-Plus), 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-C3 disc to the C7-T1 disc, 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). The cervical device is 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, such as Streamline OCT, SlimFuse, Cequence, PAC, or Aspect 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.

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Indications for Use

510(k) Number (if known)
K150521

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

Indications for Use (Describe)

LUMBAR INTERBODY FUSION DEVICE

When used as a lumbar intervertebral body fusion device (Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, and CrossFuse II), 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, 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 graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level, such as Quantum, Streamline TL, Contact ALP, Streamline MIS Systems, or Lat-Fuse Lateral Plate System.

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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Indications for Use

510(k) Number (if known)
K150521

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

Indications for Use (Describe)

VERTEBRAL BODY REPLACEMENT

When used as a vertebral body replacement (VBR) device (C-Plus, Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, and CrossFuse II), the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System ("IBF/VBR System") is intended for use in the thoracolumbar spine (T1-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 must be used with supplemental fixation cleared for the conditions listed above (i.e., tumor or trauma of T1-L5) such as the Streamline TL Spinal Fixation System, Streamline MIS Spinal Fixation System or Quantum Spinal Fixation System. Additionally, the VBR device 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)

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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
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Ph: (386) 418-8888
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Prepared: April 16, 2015

Name: Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

Trade names: C-Plus, Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, CrossFuse II, CrossFuse II Coronal Taper, CrossFuse 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 K133455

Additional Predicate Devices: Pioneer IBF/VBR System (K043206, K061151, K073177, K112496, and K133623)
NuVasive® CoRoent® Small Contoured Interbody System (K142050)

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 of open or minimally invasive approaches, including anterior, lateral, posterior and oblique.

The purpose of this submission is to expand the indication for use to

include the use of allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft as an alternative to autogenous bone graft for use with the predicate C-Plus device in cervical intervertebral body fusion. No changes were made to the C-Plus implants.

Class I and 510k exempt orthopedic manual surgical instruments are also available for use with the System.

Indications for
Use:

CERVICAL INTERBODY FUSION DEVICE

When used as a cervical intervertebral body fusion device (C-Plus), 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-C3 disc to the C7-T1 disc, 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). The cervical device is 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, such as Streamline OCT, SlimFuse, Cequence, PAC, or Aspect Systems.

LUMBAR INTERBODY FUSION DEVICE

When used as a lumbar intervertebral body fusion device (Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, and CrossFuse II), 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, 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 graft to facilitate fusion. IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level, such as Quantum, Streamline TL, Contact ALP, Streamline MIS Systems, or Lat-Fuse Lateral Plate System.

VERTEBRAL BODY REPLACEMENT

When used as a vertebral body replacement (VBR) device (C-Plus, Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, and CrossFuse II), the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System (“IBF/VBR

System”) is intended for use in the thoracolumbar spine (T1-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 must be used with supplemental fixation cleared for the conditions listed above (i.e., tumor or trauma of T1-L5) such as the Streamline TL Spinal Fixation System, Streamline MIS Spinal Fixation System or Quantum Spinal Fixation System. Additionally, the VBR device is intended to be used with bone graft.

Summary of
Technological
Characteristics:

The purpose of this 510(k) submission is to seek clearance for the use of allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft as an alternative to autogenous bone graft for cervical interbody fusion devices previously cleared via K133455. No changes have been made to the actual implants.

Performance Data
Supporting
Substantial
Equivalence
Determination:

A literature analysis of published clinical data for the cervical interbody fusion devices similar to the predicate device, C-Plus (K133455), 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, cortical, and/or corticocancellous bone graft, in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above poses no new risks to patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

Conclusion:

The intended use, design features, materials used in manufacturing and sterilization methods are substantially equivalent to the previously cleared, predicate C-Plus device.