K133455

MAR 2 7 2014

510(k) Summary Pursuant to 21 CFR 807.92

Sponsor: Pioneer Surgical Technology, Inc. (RTI Surgical, Inc.)
375 River Park Circle
Marquette, MI 49855 USA
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Prepared: March 25, 2014

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

Trade names: C-Plus, Rotate, Bullet-Tip, T-Plus, Contact, CrossFuse, & CrossFuse II

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: Orthopaedic and Rehabilitation Devices Panel; Panel Code 87

Predicates: Pioneer IBF/VBR System K112496 &K133623
Pioneer IBF System K073177
Pioneer VBR System K043206 & K061151
NuVasive CoRoent System (K071795)

Description: The Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System consists of a variety of different footprints and heights which enable the surgeon to choose the implant best suited to an individual's pathology and anatomical condition. Supplemental anterior and/or posterior fixation is intended for use with the device to ensure stability of the spine and adequate compression of the implant. The IBF/VBR implants may be implanted via a variety or open or minimally invasive approaches, including anterior, lateral, posterior and oblique.

The components are manufactured from a radiolucent polymer (PEEK Optima®) in order to allow radiographic imaging inside the implant to evaluate fusion status.

The purpose of this submission to add implant configurations to the CrossFuse II line of implants, intended for lumbar IBF and VBR use.

Class I (exempt) orthopedic manual surgical instruments, including the Clarity Retractor System, are also available for use with the System.

Intended Use:

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 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.

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.

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.

Pre-Clinical Performance Data:	For a determination of substantial equivalence, static compression and static torsion testing was performed in accordance with ASTM F2077. In addition, static subsidence testing per ASTM F2267 and static expulsion testing per Draft Standard Z8423Z were performed. Mechanical testing showed that the mechanical strength of the subject system is substantially equivalent to a legally marketed predicate and sufficient for the intended use. Additional sizes and configurations outside the range of previously cleared devices were justified based on an anatomic rationale.
Materials:	The Pioneer IBF/VBR System implants are composed of ASTM F 2026 Polyetheretherketone (PEEK) with ASTM F560 tantalum or ASTM F 136 Titanium alloy radiographic markers.
Summary of Technological Comparison:	The subject implants are unique from the predicate CrossFuse II implants in that they include a coronal taper or increased lordotic angle (hyperlordotic). This submission supports the position that the subject implants are substantially equivalent to previously cleared IBF/VBR devices. The subject and predicate devices are similar in terms of indications for use, material composition, sterilization, packaging, technological characteristics, design features, and mechanical strength.
Substantial Equivalence	There are no significant differences between the subject and predicate devices which would adversely affect the use of the product. Any differences were not considered significant based on mechanical bench testing.

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

March 27, 2014

Pioneer Surgical Technology, Incorporated
Ms. Emily Downs
Director, Regulatory and Clinical Affairs
375 River Park Circle
Marquette, Michigan 49855

Re: K133455
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 14, 2014
Received: February 18, 2014

Dear Ms. Downs:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

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 on last page.

510(k) Number *(if known)*
K133455

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

Indications for Use *(Describe)*
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 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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

PSC Publishing Services (301) 443-6740 EF

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Food and Drug Administration

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Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133455

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

Indications for Use *(Describe)*
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.

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Food and Drug Administration

Indications for Use

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Expiration Date: January 31, 2017
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510(k) Number *(if known)*
K133455

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

Indications for Use *(Describe)*
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.

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