



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

Intelligent Implant Systems, LLC
Michael Nutt
Chief Operations Officer
3300 International Airport Drive, Suite 1100
Charlotte, North Carolina 28208

February 24, 2017

Re: K163056

Trade/Device Name: Revolution™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 30, 2017
Received: January 31, 2017

Dear Mr. Nutt:

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

Indications for Use Statement

510(k) Number (if known): K163056

Device Name: Revolution™ Spinal Fixation System

Intended Use / Indications for Use:

The Revolution™ Spinal Fixation System is intended for pedicle screw fixation of the non-cervical, posterior spine in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation), (4) spinal stenosis, (5) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Intelligent Implant Systems' Revolution™ Spinal Fixation System Additional Components

I. Submitter: Intelligent Implant Systems, LLC
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Date Prepared: January 30, 2017

II. Device

Name of Device: Revolution™ Spinal Fixation System

Common or Usual Name: Spinal Fixation System

Classification Name: Thoracolumbosacral pedicle screw system (21 CFR 888.3070)

Regulatory Class: II

Product Codes: NKB

III. Predicate Devices

Primary Predicate:

Intelligent Implant Systems: Revolution™ Spinal System (K142939)

Additional Predicates:

Intelligent Implant Systems: Revolution™ Spinal System (K160216)

Spinal Innovations Ascend with Shadow Spinal Fixation System (K013196)

IV. Device Description

The previously cleared Intelligent Implant Systems' Revolution™ Spinal Fixation System consists of monoaxial bone screws of various lengths and diameters and a series of connector assemblies for connecting the bone screws.

The standard (one level) Revolution™ Connectors are provided in various lengths and are used to connect the pedicle screws and create a rigid structure. To allow for variation in screw placement, each end of the connector allows for angular compensation. One end allows for full polyaxial angulation, similar to a typical polyaxial screw. The other end has a pivoting-slide that allows for angulation in only one plane along the long axis of the Connector while also sliding within an opening in the Connector. As the distance between two screws is always variable, the slide allows the Connector to compensate for this difference, minimizing inventory. In addition, the Connectors have a threaded locking nut built into each end and each nut fits over the top of a bone screw post. These locking nuts are turned clockwise to tighten. A calibrated torque wrench provides the correct setting for locking the nuts on the bone screw post with sufficient force. The system can be unlocked, if necessary, by turning the locking nuts counterclockwise. To allow for multiple level fusions, four additional components were added to the system (K160216): 1) Transition Bone Screws, 2) Transition Connectors, 3) Two-Post Connectors, and 4) Two-Post Bone Screws. These components provide two connector attachment posts with a single bone screw, which allows the attachment of two connectors (one superior, one inferior) to a single level of the spine. In the case of the Transition Connector, the Transition Bone Screw includes a connector attachment post.

This 510(k) submission adds two types of components to the system: 1) Two-Level Connectors, and 2) Two-Level Bone Screws. These components, when utilized with the previously cleared, standard Revolution™ connectors and standard bone screws, allow stabilization of two levels of the spine. These new Two-Level components allow fusion of two spinal levels when the patient's inter-pedicular distances are very short, by allowing attachment of two connector interfaces to a single bone screw. Like the previously cleared Revolution™ bone screws, the Two-Level Bone Screws are available in diameters of 4.5 mm – 7.5 mm, and in lengths from 25 mm to 55 mm. All screw diameter sizes except for the 4.5mm are cannulated for use with a 1.4 mm k-wire.

The Two-Level Bone Screws have a standard thread for interfacing bone and a partially threaded post designed to engage a standard (one level) connector and a Two-Level Connector. The Two-Level Connector uses the same technology (the pivoting-slide and the spherical bearing), and has a stepped central plate. The step in the plate allows two connectors to stack on top of each other, thus requiring less horizontal space to attach two connectors.

All implant components of the Revolution™ Spinal Fixation System, including the additional components, are manufactured from Ti-6Al-4V ELI alloy, conforming to ASTM F136.

With the addition of the new Two-Level Bone Screws and Connectors, the indications for use remain identical to those of the Revolution™ Spinal Fixation System (K142939 and K160216) predicate devices.

V. Intended Use / Indications for Use

Intended Use:

The Revolution™ Spinal Fixation System implants are intended to be used as a construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during posterior fusion procedures, attaching to the spine by means of monoaxial bone screws joined with a connector.

Indications for Use:

The Revolution™ Spinal Fixation System is intended for pedicle screw fixation of the non-cervical, posterior spine in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation), (4) spinal stenosis, (5) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

VI. Comparison of Technological Characteristics with the Predicate Devices

The Revolution™ Spinal Fixation System Two-Level components and the predicate devices are all posterior systems utilizing pedicle fixation for stabilization of spinal segments. At a high level, the subject and predicate devices all have the following technological characteristics:

- Bone thread used to implant bone screws in pedicles
- Lock nuts or bolts used to attach bone screws to plates or rods
- Torque is applied to lock nuts or bolts to secure assemblies

The following technological differences exist between the subject and predicate devices:

- The additional components provide two connector attachment points at one level, which are then used to attach to multiple connectors instead of using longer plates or rods attached by additional bolts or screws.

VII. Performance Data

The following performance data were provided on the two-level components in support of the substantial equivalence determination:

Mechanical Testing:

To validate the strength and safety of the additional Two-Level components, testing was conducted according to methods defined in ASTM F 1798-13, “Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants”, and ASTM F 1717-15, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. The types of testing performed on the multi-level components are listed below:

Testing per ASTM F1798-13

1. Static Flexion-Extension Strength
2. Anterior Posterior (A-P) Pullout Strength

Testing per ASTM F1717-15

1. Static Compression Bending
2. Static Torsional Bending
3. Dynamic Compression Bending

The testing revealed that the mechanical properties of the additional Two-Level components are comparable to existing Revolution™ Spinal Fixation System components and to published values for rod systems.

Materials: All components of the Revolution™ Spinal Fixation System Two-Level components are machined from Ti-6Al-4V ELI, conforming to ASTM F-136.

Pyrogenicity Testing: Pyrogen testing of Revolution Spinal System components has shown that the implants conform to pyrogen requirements and batch testing on each production lot will be performed.

Summary: Based on the mechanical testing that was performed and the composition of the device, the Revolution™ Spinal Fixation System two-level components were found to be substantially equivalent to the predicate devices.

VIII. Conclusions

The additional Revolution™ Spinal Fixation System components have a design similar to the predicate devices, function in a similar manner, and their mechanical properties are comparable. Thus, the Revolution™ Spinal Fixation System Two-Level components should perform as intended in the specified use conditions.