K102248

1.0 510(k) Summary

Prepared October 5, 2010

Company:
Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact:
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OCT 7 2010

Trade Name:
Excella® Spinal System
Excella-M
Excella-P
Excella II™

Common Name:
Pedicle Screw Spinal System

Classification:
Regulation No.: 21CFR 888.3050, 3060. Class II
Regulation No.: 21CFR 888.3070, Class III
Product Code: NKB, KWP, KWQ, MNI, MNH
Review Panel: Orthopedic
Applicable Standards:

- ASTM F543-07 Standard Specification and Test Methods for Metallic Medical Bone Screws.
- ASTM F1717-09 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- ASTM F1798-97(Reapproved 2008) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- ASTM F2193-02(Reapproved 2007) Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

Substantially Equivalent Device:
K071921 Excella® Spinal System

Device Description:
The Excella II™ Spinal System consists of 6AL-4V Titanium alloy implants meant to be used in a system. The single use devices are offered in a variety of different

lengths ranging from 25mm to 60mm as well as the following diameters, 4.75mm, 5.5mm, 6.5mm and 7.5mm, 8.5mm—and are sold non-sterile. The Excella II implants are cannulated and feature a multi-axial joint for free motion of the screw head to allow the physician greater flexibility when placing the screws, including use of a minimally invasive surgical procedure. The bone thread portion of the screws features a self-tapping, double lead with an aggressive thread.

The Excella II system utilizes 5.5mm Titanium rods in various lengths from 35mm to 460mm (straight) or 35mm to 85mm (bent). The rods are placed in the head of the screws and the system is locked in place with Titanium locking caps. The locking caps design includes a threaded locking screw attached to an alignment cap. Each locking cap includes a buttress thread design for axial strength and to prevent screw loosening. The alignment cap is attached to the bottom of the locking screw and rotates about the radial axis. This cap is intended to aid the alignment of the locking cap during insertion. The alignment cap also improves the rotational stiffness at the rod to locking cap interface.

The Excella II system also has available alignment caps with extended length head (reduction head) that can be broken off after installation. The available lengths go from .5 inches (12.7mm) to 4.72 inches (120mm). Primarily used in scoliosis correction, the reduction head allows easier use of longer rods that may be difficult to place in the standard head due to the anatomy of the patient and the curvature of the spine needing correction. A retaining ring is provided to prevent splay of the reduction head while tightening down the rod. Once the locking screw has been tightened in place, the ring is removed and the added length on the alignment cap can be broken off at a tab, resulting in a final profile and assembly that is identical to a standard screw and locking cap assembly.

The cross connectors come in various adjustable lengths and allow for variation in perpendicular placement on two rods. Each cross connector features a clamping mechanism to grip the rods and stabilize the relation between the rods.

Performance Data: (Non-clinical)—Performance testing per ASTM F543, F1717 and F1798 for Static Compression Bend, Static Torsion and Dynamic Compression Bend, Axial Pullout Strength, Torque to Failure, Axial, Flexion and Torsional Grip indicates that the Excella II Spinal System is capable of performing in accordance with its intended use.

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Materials: The implants are machined from Medical Grade Titanium (6AL-4V) per ASTM F136-02a.

Intended Use: The intended use is the same as the predicate Excella® Spinal System (K071921). The Innovasis® Excella II™ Spinal System is intended for use in the non-cervical area of the spine.

Indications for Use: The intended use is the same as the predicate Excella® Spinal System (K071921).

The Excella Pedicle Screw System, when used for pedicle screw fixation is intended only for patients:

a) Having severe spondylolisthesis (Grade 3 & 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Excella Pedicle Screw System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic deformities of the thoracic, lumbar, and sacral spine:

a) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Previous failed fusion (pseudoarthrosis).

The Excella Pedicle Screw System, when used for anterolateral non-pedicle fixation, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis;
c) Spondylolisthesis;
d) Spinal deformities (*i.e.*, scoliosis, kyphosis, and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation); and

h) Previous failed fusion.

The Excella Pedicle Screw System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis;
c) Spondylolisthesis;
d) Spinal deformities (*i.e.* scoliosis, kyphosis and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation);
h) Previous failed fusion.

Contraindications (Exclusions for Use):

a.) Morbid obesity
b.) Mental illness
c.) Alcoholism or drug abuse
d.) Pregnancy
e.) Metal sensitivity / allergies
f.) Severe osteopenia
g.) Active infection near the surgical site
h.) Patients unwilling or unable to follow post-operative care instructions

Basis for Substantial Equivalence:

The Excella II Spinal System has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the predicate device, K071921, Excella Spinal System.

Design configurations are substantially equivalent.

Applied mechanical loads are substantially equivalent.

Product sizes and shapes are substantially equivalent.

Materials used are equivalent.

Biocompatibility requirements are equivalent.

Manufacturing and processing methods are substantially equivalent.

Training of Physicians and Representatives is substantially equivalent.

Indications for Use are equivalent.

Shelf life is equivalent.

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Summary of Safety And Effectiveness: The Innovasis Excella II Spinal System is shown to be safe and effective for use as a polyaxial pedicle screw system and in the indications associated with device product codes KWP, MNH, MNI and NKB.

Safety: The following have been performed to ensure the safety of the product:

Use of biocompatible materials that have a proven history of acceptable performance.

Material selection with certifications to ASTM F136.

Additional biocompatibility testing verification (LAL, MEM analysis)

Mechanical testing performed to applicable ASTM standards.

Effectiveness: The following have been performed to ensure the effectiveness of the product:

Dimension verification (inspection) to the design.

Process verification and validation.

Product verification and validation.

Physician evaluation

Calibrated inspection systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 7 2010

Innovasis, Inc.
% Mr. Marshall C. McCarty
Manager QA/RA
614 East 3900 South
Salt Lake City, Utah 84107

Re: K102248
Trade/Device Name: Excella II™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: September 10, 2010
Received: September 13, 2010

Dear Mr. McCarty:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

Indications for Use Statement

510(k) Number: K102248

Device Name: Excella® Spinal System

Indications for Use:

The Innovasis® Excella® Spinal System is **intended for use** in the non-cervical area of the spine.

The INNOVASIS® Excella® Spinal System, when used for pedicle screw fixation is intended only for patients: a) Having severe spondylolisthesis (Grade 3 & 4) at the L5-S1 joint; b) Who are receiving fusion using autogenous bone graft only; c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and d) Who are having the device removed after the development of a solid fusion mass.

The INNOVASIS® Excella® Spinal System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic deformities of the thoracic, lumbar, and sacral spine:

i. Degenerative spondylolisthesis with objective evidence of neurologic impairment;
ii. Fracture;
iii. Dislocation;
iv. Scoliosis;
v. Kyphosis;
vi. Spinal tumor; and
vii. Previous failed fusion (pseudoarthrosis).

Prescription Use X (21 CFR 801 Subpart D) OR Over-The-Counter-Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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The INNOVASIS® Excella® Spinal System, when used for anterolateral non-pedicle fixation, is intended for the following indications:

i. Degenerative disc disease*
ii. Spinal stenosis;
iii. Spondylolisthesis;
iv. Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
v. Pseudoarthrosis
vi. Tumor
vii. Trauma (i.e. fracture or dislocation); and
viii. Previous failed fusion.

*(defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).

The INNOVASIS® Excella® Spinal System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

i. Degenerative disc disease;
ii. Spinal stenosis;
iii. Spondylolisthesis;
iv. Spinal deformities (*i.e.* scoliosis, kyphosis and/or lordosis);
v. Pseudoarthrosis
vi. Tumor;
vii. Trauma (i.e. fracture or dislocation);
viii. Previous failed fusion.

*(defined as back pain of disogenic origin with degenerative disc confirmed by patient history and radiographic studies).

Prescription Use X (21 CFR 801 Subpart D) OR Over-The-Counter-Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number K102248

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