K121581

Section 5 Box™ PEEK IBF System 510(k) Summary Report

September 12, 2012

OCT 17 2012

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

Contact: Marshall C. McCarty
Phone: (801)261-2236
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Trade Name: Box™ PEEK IBF System

Common Name: Interbody Fusion Device

Classification: Product Code: MAX
Regulation Number: 21 CRF 888.3080
Classification Name: Intervertebral Body Fusion Device
Panel code: 87

Substantially Equivalent Devices:
- K062151 – Box PEEK VBR System—Innovasis, Inc.
- P960025 – Jaguar Lumbar I/F Cage System—DePuy Spine, Inc.

Intended Use: The Innovasis *Box PEEK IBF System* is an intervertebral body fusion device intended to stabilize a spinal segment to promote fusion using bone graft, in order to restrict motion and decrease pain.

Indications for use are as follows:

The Innovasis *Box PEEK IBF System* is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via either an anterior or anterolateral (*A-Box*) or lateral (*L-Box*) approach.

This device is intended to be used with internal supplemental spinal fixation systems such as the Innovasis *Excella® Spinal System*. The interior of the Box implants is intended to be packed with autograft.

Device Description:

The Innovasis *Box™ Peek IBF System* consists of polyetheretherketone (PEEK) implants meant to be used with supplemental fixation and offered in a variety of different sizes, in order to accommodate the patient's anatomy and surgeon's preference for installation. The implants feature holes in the interior geometry in order to accommodate bone graft and maximize bone

ingrowth. Tantalum (*A-Box*) or titanium (*L-Box*) radiographic markers are incorporated into the material to allow for visualization of the implant configuration during and after surgery. The surfaces of the implants have machined barbs meant to engage the vertebral endplates and prevent expulsion.

The *A-Box* device is an anatomically shaped IBF with two interior holes to allow for packed autograft. This device is designed to be inserted from an anterior or anterolateral approach.

The *L-Box* device is similar to the *A-Box*, but is longer and designed to be inserted from a lateral approach. It has a rounded nose which can be used to aid in placement.

Materials: The implants are machined from Medical Grade PEEK (Polyetheretherketone) Zeniva™ (Solvay) per ASTM F2026. Marker beads (*A-Box*) machined from implant grade Tantalum per ASTM F560. Marker pins (*L-Box*) machined from implant grade Titanium per ASTM F-67.

The system comes with reusable stainless steel surgical instruments designed to be cleaned and steam-sterilized between uses. These instruments aid in the preparation of the area and installation of the PEEK implants.

Performance Data—*Non-clinical (Bench)*:

The standard ASTM F2077 is recognized by FDA and internationally as a uniform method for testing Intervertebral Body Fusion Devices, and the results can be compared to other devices. Testing to this standard can assess the mechanical behavior of the device.

This method simulates the loads that will be seen in an implant application, *i.e.* compressive loads are parallel to the axis of the spine and torsional loads rotate around the axis of the spine.

The standard ASTM F2267 is a recognized standard method to determine subsidence of an IVBFD for comparison purposes.

Testing protocols and acceptance criteria were defined prior to testing in various documents filed in the Design History Files for these products.

Performance bench testing has been conducted on sterilized samples of the identified "worst case" sizes from the *Box™ PEEK IBF System* (*A-Box* and *L-Box*). Worst case was determined using Finite Element Analysis. The testing included: Static Axial Compression, Static Torsion (ultimate torque), Offset Yield Torque (all per F2077-11), Expulsion (per in-house method) and Subsidence (per F2267-04).

Biocompatibility

PEEK has a substantial history and laboratory evidence of biocompatibility. In order to verify that the processing at Innovasis does not introduce new biocompatibility issues, Limulus Amebocyte Lysate (LAL) and MEM Elution tests have been performed on representative *A-Box* and *L-Box* devices. The devices were manufactured per Innovasis specifications and procedures, then were submitted for testing. All tests passed well below the cutoff limit.

Sterilization Validation

Autoclave (steam) sterilization validation was performed by an independent contractor on the *A-Box IBF* and Instruments in the carrying case. This is the worst case configuration for the *Box*

IBF products, because all instruments and implants are included in one case, presenting a large mass and heat sink.

Pre-vacuum and gravity steam sterilization per parameters in the Innovasis IFU were validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator overkill method for both the *A-Box* and *L-Box* systems.

Conclusion
The Box PEEK IBF implants, the *L-Box* and *A-Box*, were substantially equivalent to predicate devices and met the acceptance criteria for each test. The worst-case implants performed substantially equivalent to the predicates for multiple modes of loading and met all of the acceptance criteria. The Innovasis Inc. *A-Box* and *L-Box* IBF will adequately stabilize the lumbar spine for an interbody fusion indication as it demonstrated favorable mechanical performance compared to legally marketed predicate device.

Performance testing indicates that the *Box™ Peek IBF System* is capable of performing in accordance with its intended use.

Basis for Substantial Equivalence:

The *Box™ Peek IBF System* has been subjected to risk analysis and engineering analysis including recognized ASTM standard testing and has been shown to be substantially equivalent to the predicates:

- K062151 – Box Peek VBR System—Innovasis, Inc.
- P960025 – Jaguar Lumbar I/F Cage System (Brantigan Cage)—DePuy Spine, Inc.

Summary of Safety and Effectiveness:

The Innovasis *Box™ Peek IBF System* is shown to be substantially equivalent for use as a intervertebral body fusion device and in the indications associated with device product code MAX.

For the new additions to the product line, the worst-case implants performed substantially equivalent to the predicates for multiple modes of loading and met all of the acceptance criteria. The Innovasis Inc. *A-Box* and *L-Box* IBF will adequately stabilize the lumbar spine for an interbody fusion indication as it demonstrated favorable mechanical performance compared to legally marketed predicate device.

Analysis of the intended use, design, materials and physical characteristics has shown the *Box™ PEEK IBF System* to be substantially equivalent when compared to the predicate devices. Based on feature comparisons, performance testing, indications for use, and adherence to good laboratory practice, Innovasis believes the *Box™ PEEK IBF System* to be substantially equivalent to existing legally marketed devices.

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

Innovasis, Incorporated
% Mr. Marshall C. McCarty
Manager, Regulatory Affairs
614 East 3900 South
Salt Lake City, Utah 84107

OCT 17 2012

Re: K121581
Trade/Device Name: Box™ PEEK IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 11, 2012
Received: September 14, 2012

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.

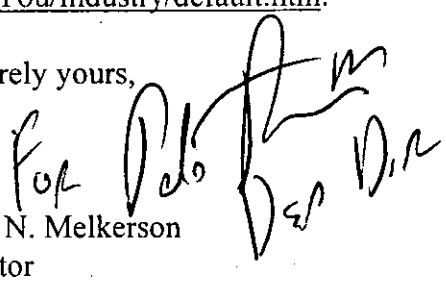
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Section 4 Indications for Use Statement

510(k) Number: K121581

Device Name: Box™ PEEK IBF System

Indications for use are as follows:

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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

510(k) Number K121581