510k Summary Statement: OCT 7 - 2004 K042143

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

Name of Firm: Innovasis, Inc.
997 East 3900 South, Suite 103
Salt Lake City, Utah 84124

510(k) Contact: Brent A. Felix
Same address as above

Trade Name: 'Excella-M' Spinal System

Common Name: Rod and Screw Spinal Instrumentation

Classification: Spinal Intervetebral Body Fixation Orthosis (21 CRF 888.3060)
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)
Spondylolisthesis Spinal Fixation System (21 CRF 888.3070)
Pedicle Screw Spinal System (21 CRF 888.3070)

Device Product Code: KWQ, KWP, MNH, MNI. The Panel code is 87.

Substantially Equivalent Devices: Blackstone Spinal Fixation System (k994217)
DePuy Acromed Moss Miami system (k992168)
Synthes Universal Spinal System (k990745)
Interpore Cross Synergy IQ Spinal System (k012871)

Device Description:

The INNOVASIS 'Excella-M' Spinal System is a 6-4 Titanium Alloy device comprised of a variety of non-sterile, single use components of 2 size diameters (6.5 & 7.5mm) and various lengths of monoaxial Pedicle Screws with an assortment of various lengths 6.0mm Rods.

The INNOVASIS 'Cross Link' is a modification to the 'Excella-M' Spinal System that allows the surgeon to build a spinal implant construct to increase rotational stability.

The system is attached to the vertebral body by means of screws to the non-cervical spine.

The INNOVASIS 'Excella-M' Spinal System consists of an assortment of screws, rods, cross-connector and related instrumentation as implant offerings specific to this system.

Intended Use:

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

Indications for use are as follows:

The INNOVASIS 'Excella-M' Spinal System, when used for pedicle screw fixation is intended only for patients:

a) Having severe spondyloysthesis (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-M' 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:

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

The INNOVASIS 'Excella-M' Spinal 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 studie);
b) Spinal stenosis; c) Spondylolisthesis; d) Spinal deformities (i.e., scloliosis, kyphosis, and/or lordosis),
e) Pseudarthrosis; f) Tumor; g) Trauma (i.e. fracture or dislocation); and
h) Previous failed fusion.

The INNOVASIS 'Excella-M' Spinal 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 disogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis; c) Spondylolisthesis; d) Spinal deformities (i.e. scolosis, kyphosis and/or lordosis);
e) Pseudoarthrosis; f) Tumor; g) Trauma (i.e. fracture or dislocation); and
h) Previous failed fusion.

K042143

Material:

The Innovasis 'Excella-M' Spinal System is made from 6-4 Alloy Titanium (ASTM F 136).

These materials are proven to be biocompatible as implant materials.

Performance Data:

Mechanical testing in accordance with the "Guidance for Industry and FDA Staff Spinal System 510(k)s", issued May 3, 2004 was presented.

Basis of Substantial Equivalence:

The Innovasis 'Excella-M' Spinal System is similar to the predicate the Blackstone Spinal Fixation System (k994217), DePuy Acromed Moss Miami System (k992168), Synthes Universal Spinal System (k990745), and Interpore Cross Synergy IQ Spinal System (k012871) with respect to technical characteristics and performance.

Summary of Safety and Effectiveness:

The Innovasis 'Excella-M' Spinal System is shown to be safe and effective for use in certain antierior and pedicle fixation use indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. Brent A. Felix
President
Innovasis, Inc.
997 East 3900 South, Suite 103
Salt Lake City, Utah 84124

Re: K042143
Trade/Device Name: ' Excella-M' Spinal System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWQ, KWP, MNH, MNI
Dated: July 30, 2004
Received: August 9, 2004

Dear Mr. Felix:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INNOVASIS, INC
997 East 3900 South, Suite 103
Salt Lake City, Utah 84124
(801) 557-1445
(801) 424-2097 Fax

Indications for Use

510(k) Number: K042143

Device Name: 'Excella-M' Spinal System

Indications for Use:

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

The Innovasis 'Excella-M' 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 sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Innovasis 'Excella-M' 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: 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 (pseudarthrosis).

The Innovasis 'Excella-M' Spinal System, when used for anterolateral non-pedicle fixation, is intended for the following indications:
a)Degenerative disc disease (DDD) (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) Pseudarthrosis; f) Tumor; g) Trauma (i.e. fracture or dislocation); and h) Previous failed fusion.

The Innovasis 'Excella-M' Spinal System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:
a) Degenerative disc disease (DDD) (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) Pseudarthrosis; f) Tumor; g) Trauma (i.e. fracture or dislocation); and h) Previous failed fusion

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous
info@innovasissurgical.com
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042143