JUN 30 2006

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INNOVASIS, Inc.
614 East 3900 South
Salt Lake City, UT 84107
801-261-2236
Fax 801-261-0573

Opteryx™ Anterior Cervical Plate System
510(k) Summary

March 24, 2006

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

Contact: David N. McKean
Phone: (801)261-2236
Fax: (801) 261-0573

Trade Name: Opteryx™ Anterior Cervical Plate System

Common Name: Anterior cervical fixation system and Instrumentation

Classification: KWQ 888.3060 - Spinal intervertebral body fixation Orthosis. Panel code: 87

Substantially Equivalent Devices:
- Synthes 'CSLP' Cervical Spine Locking Plate (K000536),
- Theken 'Tether' Anterior Cervical Fixation System (K050451),
- Medtronic 'Zephir' Anterior Cervical Plate System (K994239),

Device Description:

The Innovasis 'Opteryx' Anterior Cervical Plate System is a 6Al-4V ELI Titanium Alloy device comprised of an anterior cervical fixation plate and various screws. The purpose of this device is to stabilize the anatomical positioning of the cervical vertebrae after surgery.

The cervical plates will be available in a variety of sizes to allow for the treatment of a wide variety of differing cases. Screws of different types will be included in the sets as well. Fixed angle screws will be included for cases when it is important to maximize stability. Variable angle screws will be included to allow the physician greater flexibility when placing the plates and securing it to the vertebrae. Differing lengths of screws will be provided in both the fixed and variable configurations, to allow for Unicortical or bicortical purchase.

Performance Data: Non-clinical:
Static and fatigue testing was performed.
Properties of stiffness, strength, and fatigue life were characterized.

Material:

The Innovasis Opteryx™ Anterior Cervical Plate System is made from 6Al-4V ELI Alloy Titanium per ASTM F136. This material has been proven to be biocompatible as an implant material.

INNOVASIS, Inc.
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Intended Use:

Indications for use are as follows:

The Innovasis Opteryx™ Cervical Plate System is intended for use in anterior cervical fixation for the following indications:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudoarthrosis; and
- Previous failed fusion.

The Innovasis Opteryx™ Anterior Cervical Plate System is indicated for stabilizing the cervical spine from C2 to C7.

Basis for Substantial Equivalence:

Anterior cervical plate fixation systems are a commonly used product in spinal orthopedics and the mechanical aspects and performance characteristics of such devices are widely known. The 'Opteryx' Anterior Cervical Plate System has been subjected to risk analysis and testing per ASTM F1717 and been shown to be substantially equivalent to the predicates:

- Synthes 'CSLP' Cervical Spine Locking Plate (K000536),
- Theken 'Tether' Anterior Cervical Fixation System (K050451),
- Medtronic 'Zephir' Anterior Cervical Plate System (K994239),

with regards to indications for use, technology and performance.

Summary of Safety and Effectiveness:

The Innovasis Opteryx™ Anterior Cervical Plate System is shown to be safe and effective for use in anterior cervical fixation and the indications associated with device product code KWQ.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2006

Innovasis, Inc.
% Mr. David McKean
Vice President of Operations
614 East 3900 South
Salt Lake City, Utah 84107

Re: K061147
Trade/Device Name: Opteryx™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis.
Regulatory Class: Class II
Product Code: KWQ
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. McKean:

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.

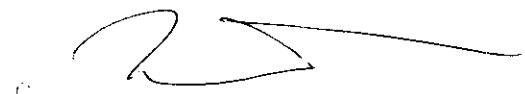
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications of Use Statement

510(k) Number: K061147

Device Name: Opteryx™ Cervical Plate System

Indications for use are as follows:

The Innovasis Opteryx™ Cervical Plate System is intended for use in anterior cervical fixation for the following indications:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation)
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- Tumor,
- Pseudoarthrosis, and/or
- Previous failed fusion.

The Innovasis Opteryx™ Anterior Cervical Plate System is indicated for stabilizing the cervical spine from C2 to C7.

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 General, Restorative, and Neurological Devices

510(k) Number K061147