K071420

SPINEFRONTIER™
WHERE SURGEONS INNOVATE

510 (k) Summary

JAN 16 2008

Date Prepared [21 CFR 807.92(a)(1)]

5/21/07 **Revised 10-17-2007**

Submitter's Information [21 CFR 807.92(a)(1)]

Contact
Tom Carlson
SpineFrontier, Inc.
100 Cummings Center, Suite 240C
Beverly, Massachusetts 01915
Phone: 978-232-3990
Fax: 978-232-3991

FDA Establishment Registration# 3005977257

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- ***CHAMELEON*™ Fixation System**

Device Common, Usual, or Classification Names

System facet Screw Spinal Device

Classification

Unclassified, Product Code MRW

Predicate Device [21 CFR 807.92(a)(3)]

Depuy Discovery – K012773

Nuvasive Inc. - Townley Transfacet Screw – K994308

Description of the Device [21 CFR 807.92(a)(4)]

The SpineFrontier, Inc. ***CHAMELEON™* Fixation System** is designed to provide bilateral, transfacet fixation of the spinal facet joint in the lumbar spine.

The facet screw included in the ***CHAMELEON™* Fixation System** is a partially threaded 4.5mm diameter screw offered in lengths of 30-50mm (in 5mm increments). The device is composed of medical grade Titanium (Ti6Al4V) that complies with ASTM F-136. The devices are offered with a built in washer or without a washer.

Washers: Integral to the screw design, washers increase the load bearing area of the screw in contact with the bone. These washers are designed to angulate about the head of the bone screws to provide optimal bony contact over a range of screw trajectories.

The devices are sold non-sterile and are packaged in a clear poly bag. These devices are sterilized by a healthcare professional using Steam Autoclave in accordance to the instructions for use provided by SpineFrontier, Inc., as well as the instructions provided by the manufacturer of the Autoclave.

Intended Use [21 CFR 807.92(a)(5)]

The subject device is intended to stabilize the spine as an aid to fusion by transfacet fixation.

The subject device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels including: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm.

Technological Characteristics [21 CFR 807.92(a)(6)]

The device is substantially equivalent to the predicate devices based on comparison on physical and performance characteristics.

Performance Data [21 CFR 807.92(b)(1)]

The device is composed of biocompatible materials that have a long successful history in the orthopedic industry. The device performed well during various mechanical tests including comparison to predicate devices. The device was tested using the following standards as guidance: ASTM F-2193 (Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System) and ASTM F-543 (Standards Specifications and Test Methods for Metallic Bone Screws).

Conclusion [21 CFR 807.92(b)(3)]

We believe that the subject device is substantially equivalent and as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 16 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineFrontier, Inc.
% Mr. Tom Carlson
100 Cummings Center
Suite 240C
Beverly, MA 01915

Re: K071420
Trade/Device Name: CHAMELEON™ Fixation System
Regulation Number: Unclassified
Regulation Name: Facet screw spinal device system
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 17, 2007
Received: October 19, 2007

Dear Mr. Carlson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number K071420

Device Name: SpineFrontier Inc. – ***CHAMELEON*™ Fixation System**

Indications For Use:

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The subject device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels including: 1)Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm.

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

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