SEP 2 0 2012

510(k) Summary

Preparation Date September 15, 2012

Sponsor

Choice Spine, LP
400 Erin Drive
Knoxville, TN 37919
PH: (865)243-3969
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Contact

Kim Finch
Manager of Regulatory Affairs

Trade Name

Typhoon™ Facet Screw Fixation System

Classification and Common Name

Unclassified, Facet Screw Spinal Device System

Device Product Code

MRW

Predicates

DePuy AcroMed™ Inc. -Discovery™ Facet Screw System (K012773)
Spine Frontier Inc. -Chameleon™ Fixation Screw System (K071420)
X- Spine Systems, Inc. - Fixcet™ Spinal Facet Screw Fixation System (K100154)

Device Description

The Typhoon™ Facet Fixation System is a posterior Facet spinal fixation system consisting of screws and washers, manufactured from titanium alloy (Ti6Al4V ELI; ASTM F136). The bone screws are designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. The self-tapping screws are 4.5mm and 5.5mm in diameter. The 4.5mm screws are supplied in length ranging from 20mm to 60mm and the 5.5 mm screws range in length from 25mm to 60mm.
Washers are available to 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 screw to provide optimal bony contact over a range of screw trajectories.

Intended Use

The Typhoon™ Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1 inclusive.

The Facet Screw Fixation System is indicated for treatment of any or all of the following: degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history and radiographic studies; degenerative disease of the facets with instability; Spondylolisthesis; Spondylolysis; Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; and trauma, including spinal fractures and/or dislocations.
For transfacet fixation, the Typhoon™ Facet Fixation System screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the inferior pedicle.

Materials

The Typhoon™ Facet Fixation System implants are manufactured from Titanium alloy (Ti6Al4V) per ASTM F-136. All instrument parts that come in contact with human tissue are made from either 17-4 SS per ASTM F899 or 465 SS per ASTM F899/A564.

Substantial Equivalence

Documentation was provided that demonstrate the Typhoon™ Facet Screw Fixation System to be substantially equivalent to previously cleared device systems. The substantial equivalence is based upon equivalence in intended use, indications, anatomic location, material, and performance. Mechanical testing was performed according to ASTM F2193 "Standard Specification and Test Method for Components used in the Surgical Fixation of the Spinal Skeletal System" and ASTM F543 "Standard Specifications and Test Methods for Metallic Bone Screws". Testing parameters executed were static bending, dynamic bending, static torsion, and axial pullout.

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

Choice Spine, LP
% Ms. Kim Finch
Manager, Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

SEP 20 2012

Re: K121850
Trade/Device Name: Typhoon™Facet Screw Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 4, 2012
Received: September 5, 2012

Dear Ms. Finch:

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,

For

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: K121850

Device Name: Typhoon™ Facet Screw Fixation System

Indications for Use:

The Typhoon™ Facet Fixation Screw System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1 inclusive.

The Typhoon™ Facet Screw Fixation System is indicated for treatment of any or all of the following: degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history and radiographic studies; degenerative disease of the facets with instability; Spondylolisthesis; Spondylolysis; Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; and trauma, including spinal fractures and/or dislocations.

For transfacet fixation, the Typhoon™ Facet Screw Fixation System is inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle.

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)

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

510(k) Number K121850