8. 510(k) Summary

Preparation Date

November 11, 2010

NOV 15 2010

Sponsor

Choice Spine, LP
306 Erin Drive
Knoxville, TN 37919
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Contact

G. Todd Hawkins
Director of Regulatory Affairs/Quality Assurance

Trade Name

Choice Spine STARFIRE™ Pedicle Screw System

Common Name

Pedicle Screw Spinal System; Pedicle Screws

Regulatory Classification & Device Product Codes

888.3070

MNI - Orthosis, Spinal Pedicle Fixation
MNH - Orthosis, Spondylolisthesis Spinal Fixation
NKB - Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease

Predicate Devices

OPTIMA™ Spinal System (K024096, K031585)
Firebird™ Spinal Fixation System (K081684)
Coral™ Spinal Fixation System (K041592)
Expedium™ 6.35 Spinal Fixation System (K062174)

Device Description

The Choice Spine STARFIRE™ Pedicle Screw System is a top-loading, polyaxial screw spinal fixation system including polyaxial screws, set screws, rods, and connectors. The components are provided clean and non-sterile. Various sizes of the implants are provided.

Intended Use

The Choice Spine STARFIRE™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities

or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (DDD; defined as back 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 failed previous fusion.

Materials

The Choice Spine STARFIRE™ Pedicle Screw System implants are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136, commercially pure titanium (G2) as described by ASTM F67 and stainless steel (316 LVM) as described by ASTM F138.

Technological Characteristics

The Choice Spine STARFIRE™ Pedicle Screw System consists of a range of polyaxial screws, rods, and connectors identical to the identified predicate systems.

The Intended Use of the STARFIRE™ System is identical to the predicate systems. The STARFIRE™ System materials are similar to the predicate systems.

The STARFIRE™ Pedicle Screw System utilizes a set screw mechanism to secure the rod in the same manner as the predicate systems.

Substantial Equivalence

Documentation was provided that demonstrates the Choice Spine STARFIRE™ Pedicle Screw System to be substantially equivalent to previously cleared device systems. The substantial equivalence is based upon equivalence in intended use, indications, anatomic location, materials, and performance.

Mechanical testing was performed according to the guidelines outlined in ASTM F1717-09 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."

Static compression bending tests showed that cannulated STARFIRE pedicle screw constructs were equivalent, with respect to bending loads and stiffness, to non-cannulated predicate pedicle fixation systems.

Compression bending fatigue tests demonstrated that the cannulated STARFIRE pedicle screw constructs had equivalent or greater endurance strength compared to non-cannulated predicate pedicle fixation systems.

In static torsional tests the cannulated STARFIRE pedicle screw constructs, without cross-connectors, were able to resist loads greater than the range of resistance required for the human lumbar spine.

Test results indicate that the STARFIRE™ System is equivalent to the predicates in each of the test modes. Documentation of the testing is available in Section 16.

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
% Mr. G. Todd Hawkins
Director of Regulatory Affairs/Quality Assurance
306 Erin Drive
Knoxville, Tennessee 37919

NOV 15 2010

Re: K102204
Trade/Device Name: Choice Spine STARFIRE™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: October 21, 2010
Received: October 22, 2010

Dear Mr. Hawkins:

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

7. Indication for Use Statement

510(k) Number (if known): K102204

NOV 15 2010

Device Name: **Choice Spine STARFIRE™ Pedicle Screw System**

Indications for Use:

The STARFIRE™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

- degenerative disc disease (DDD; defined as back 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
- failed previous fusion

Prescription Use __X__ and/or Over-The-Counter Use _____
(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102204