K102995

FEB - 2 2011

510(k) SUMMARY

Spine 360
Talon Spinal System

Premarket Notification

SUBMITTED BY

Spine 360
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746
Phone: 512-364-6400 ext 5

CONTACT PERSON
Dave Lamb
Quality and Regulatory Affairs
Fax: 800-640-6045

ESTABLISHMENT REGISTRATION NUMBER 3005841736

DATE PREPARED October 1,, 2010

COMMON NAME Spinal Fixation System

PROPRIETARY NAME Talon Spinal Fixation System

CLASSIFICATION NAME and product code
CLASS II, MNI 888.3070 - Pedicle Screw Spinal System
CLASS II, MNH 888.3070 - Pedicle Screw Spinal System

PREDICATE DEVICE Talon Spinal Fixation System(K071824)
Acme Spine System (K0010044)

The Spine 360 Talon Spinal Fixation System(K102995) is substantially equivalent to the above devices.

DEVICE DESCRIPTION

The Talon Spinal Fixation System was cleared for use via K071824, and is comprised of polyaxial screws, locking plugs, spinal rods and rod to rod connectors. The Talon System can be used for single or multiple level fixations. All components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Spine 360 proposes to add new smaller diameter (4.5mm) screws in various lengths, cannulated screws in various diameters and lengths, pedicle screw spacers as well as the minimally invasive surgical technique for use with the Spine 360 Talon Spinal System. The new components are based upon the same fundamental scientific technology and do not alter the indications for use as compared to the existing system.

NONCLINICAL TEST SUMMARY

The following tests were conducted:

- Static Compression Bending and Torsion ASTM F1717-09

- Dynamic Compression Bending ASTM F1717-09

INTENDED USE

The intended use for the device is the same as the referenced system cleared K071824. The Spine 360 Talon Spinal Fixation 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 thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

SUBSTANTIAL EQUIVALENCE

The Spine 360 Spinal Fixation System proposed additional 4.5 screws, cannulated screws and spacers demonstrated equivalence or better in compression bending performance and stiffness to the predicate device listed. The dynamic compression bending fatigue strength for the Spine 360 Spinal Fixation System had already demonstrated a greater endurance strength than predicates referenced.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Spine 360 Spinal Fixation System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

CONCLUSIONS

The Spine 360 Spinal Fixation System including the smaller 4.5 screws, cannulated screws and spacers will provide stability greater than the tolerated thresholds in range of motion and stiffness limits of the human lumbar spine and will adequately stabilize a fusion site.

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

Spine 360
% Mr. Dave Lamb
Quality and Regulatory Affairs
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746

FEB - 2 2011

Re: K102995
Trade/Device Name: Talon Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: December 16, 2010
Received: January 11, 2011

Dear Mr. Lamb:

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

510(k) Number (if known): K102995

Device Name: Spine 360 Talon Spinal System

Indications for Use:

The Spine 360 Talon Spinal 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 thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102995