K101151

510(K) SUMMARY

Name of Firm

Custom Spine, Incorporated
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MAY 19 2010

Date Prepared: April 23, 2010

Official Correspondent

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Establishment Number

3005129649

Device Name

Legally Marketed Trade Name: REGENT Anterior Cervical Plate System
Common Name: Spinal Intervertbral Body Fixation Orthosis
Device Classification: Class II
Regulation Number: 21 CFR §888.3060
Device Product Code(s): KWQ

Predicate Device

REGENT Anterior Cervical Plate System (K091134)

Device Description

The REGENT Anterior Cervical Plate System is composed of various cervical plates and screws made from a Titanium alloy (Ti-6Al-4V, ASTM F-136/ISO 5832-3). The REGENT Anterior Cervical System contains multiple level plates (1 Level, 2 Level, 3 Level, and 4 Level) and various diameter screws that are either fixed or variable in nature. The plates and screws are anodized.

Indications for Use

The REGENT Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Trauma (including fractures).
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusion
- Spondylolisthesis
- Spinal Stenosis

THIS DEVICE IS ONLY TO BE USED IN SKELETALLY MATURE PATIENTS.

WARNING: THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE.

Materials

The REGENT Anterior Cervical Plate System contains implants (screws and plates) manufactured from Titanium (Ti-6Al-4V, ASTM F-136/ISO 5832-3). The system contains instruments and non-implantable devices manufactured from stainless steel.

Predicate Device Comparison

Legally Marketed Name	**REGENT Anterior Cervical Plate System**	**REGENT Anterior Cervical Plate System**
Premarket Submission	K091134	Proposed
Fixed Screw Diameter sand Lengths	4.0 mm dia – 10 mm through 20 mm 4.5 mm dia – 12 mm through 20 mm	4.0 mm dia – 10 mm through 20 mm 4.5 mm dia – 12 mm through 20 mm
Variable Screw Diameters and Lengths	4.0 mm dia – 10 mm through 20 mm 4.5 mm dia – 12 mm through 20 mm	4.0 mm dia – 10 mm through 20 mm 4.5 mm dia – 12 mm through 20 mm
Anodized	Yes (Type II)	Yes (Type II)
Cervical Plates	Level 1 Plate – 12 mm to 26 mm Level 2 Plate – 26 mm to 46 mm Level 3 Plate – 40 mm to 67 mm Level 4 Plate – 60 mm to 84 mm	Level 1 Plate – 12 mm to 26 mm Level 2 Plate – 26 mm to 46 mm Level 3 Plate – 40 mm to 67 mm Level 4 Plate – 60 mm to 84 mm

Predicate Device Comparison (Continued)

510(k)	REGENT Anterior Cervical Plate System (Proposed Device)	REGENT Anterior Cervical Plate System Cleared Device (K091134)
Characteristic		
Screw Type	Self Drilling or Self Tapping are both available for user preference	Self Tapping
Diameters/ Lengths	4.0 mm: 10mm - 20 mm 4.5 mm: 12 mm - 20 mm	4.0 mm: 10mm - 20 mm 4.5 mm: 12mm - 20 mm
Indications For Use	Same As Previously Cleared System	The REGENT Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: o Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) o Trauma (including fractures). o Tumors o Deformities or curvatures (including kyphosis, lordosis or scoliosis) o Pseudoarthrosis o Failed previous fusion o Spondylolisthesis o Spinal Stenosis THIS DEVICE IS ONLY TO BE USED IN SKELETALLY MATURE PATIENTS. WARNING: THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE.
Materials	Ti-6Al-4V (ASTM F-136,ISO 5832-3)	Ti-6Al-4V (ASTM F-136,ISO 5832-3)

Summary of Non-Clinical Test

The self drilling screws and the cleared REGENT Anterior Cervical Plates were tested in static compression bending and torsion. This was performed in accordance with ASTM F1717, "Standard Test Methods for Spinal Implants and Constructs of a Vertebrectomy Model ", and was considered substantially equivalent to the self tapping screws used in the previously cleared REGENT Anterior Cervical Plate System (K091134).

Summary of Clinical Test

Not Applicable.

Basis for Substantial Equivalence

The basis for substantial equivalence is described in this submission and is substantially equivalent to the predicate devices based on similarities in design, intended use, and material. Performance testing, design comparisons, and functional analysis conducted on these devices demonstrate that they are equivalent to the predicate devices. The addition of the self drilling screw has the following similarities

Intended Use: The proposed system has the same intended use as the previously clear

Materials: The proposed self drilling screws are made from the same material as the self tapping screw (Ti-6Al-4V, ASTM F-136, ISO 5832-3)

Lengths of the screws: The proposed lengths of the self drilling screws are provided in the same lengths and overall diameters (4.0mm and 4.5mm).

Mechanical Testing: The mechanical test results of the proposed self drilling screw device are substantially equivalent to the self tapping screw in the cleared REGENT Anterior Cervical Plate System (K091134).

Screw to plate interface: The proximal geometry of the subject self drilling screw has an identical geometry to the self tapping screw head (K091134), and result in identical interfaces between the REGENT Anterior Cervical Plate.

Modification to the device

- The addition of an acute angle tip screw (self drilling) as an alternative to the self tapping screw in the previously cleared REGENT ANTERIOR Cervical Plate System (K091134).

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

Custom Spine, Inc.
% Mr. Saad Attiyah
Manager, Regulatory Affairs and
Quality Assurance
1140 Parsippany Blvd, Suite 201
Parsippany, New Jersey 07054

MAY 19 2010

Re: K101151
Trade/Device Name: REGENT Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 20, 2010
Received: April 23, 2010

Dear Mr. Attiyah:

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 : K101151

The REGENT Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

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Prescription Use __X___ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 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

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