510(k) SUMMARY
November 2010

Submitter: Alphatec Spine, Inc.
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NOV - 5 2010

Official Contact: Karla Schaffner, Regulatory Affairs Submissions Specialist

Trade/Model Name: Trestle Luxe Anterior Cervical Plating System

Common Name: Spinal Intervertebral Body Fixation Orthosis

Classification Regulation: KWQ - Appliance, Fixation, Spinal Intervertebral Body

Device Description:

The Trestle Luxe Anterior Cervical Plating System is a temporary device used to stabilize the cervical spine during bone fusion development. Device implants include a range of plate sizes and bone screws to provide the versatility required for the specific indications noted. Fixation is achieved by means of a rigid plate that is surgically attached to the spine with bone screws.

Indications for Use

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.

The Trestle Luxe Anterior Cervical Plating system is intended for use in anterior cervical decompression and fusion (ACDF) surgery (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- 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
- pseudoarthrosis
- tumor
- and failed previous fusion.

Substantial Equivalence:

The Trestle Luxe Anterior Cervical Plating System is substantially equivalent in intended use and function to the following predicate devices.

Trade/Proprietary/Model Name	Manufacturer	510(k) #
Next Generation (Trestle) Anterior Cervical Plating System	Alphatec Spine, Inc	K070681
Slim-Loc System	Codman & Shurtleff, Inc	K013877
Venture Anterior Cervical Plate System	Medtronic, Inc	K061274

Technological Characteristics Comparison:

The Trestle Luxe Anterior Cervical Plating System is substantially equivalent to the referenced devices in that it is intended to be used to provide temporary internal cervical fixation and stabilization during bone graft healing and/or fusion mass development. The Trestle Luxe System is composed of medical grade titanium alloys conforming to ASTM F136 and ASTM F2063. The plates have an integrated screw locking mechanism to prevent screw back out. A variety of bone screws are provided for surgical convenience. It is similar in terms of general design, intended use, and technological characteristics to the predicate devices.

Nonclinical Performance Data:

No new testing was performed for the addition of the new components to the Trestle System. An evaluation of the expansion of the spinal system to include additional components substantiated that the new components used the same interconnecting mechanism and that the additional components do not cause the system to be susceptible to loosening or failure. Finally, the new components were found not to constitute a new worse case assembly.

Mechanical testing was performed previously with the 510(k) submission for K071380. This original testing provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, *Spinal System 510(k)s - Guidance for Industry and FDA Staff.* This testing documented both static and fatigue performance characteristics. This testing clearly demonstrated that the performance characteristics satisfy the requirements of anterior cervical fixation. As a result of this testing, the Trestle Luxe Anterior Cervical Plate System is substantially equivalent to the predicate devices.

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

Alphatec Spine, Inc.
% Ms. Karla Schaffner
Regulatory Affairs Submissions Specialist
5815 El Camino Real
Carlsbad, California 92008

NOV - 5 2010

Re: K102820
Trade/Device Name: Trestle Luxe 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: September 14, 2010
Received: September 28, 2010

Dear Ms. Schaffner:

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

Section 11 Indications for Use Statement

K102820

NOV - 5 2010

510(k) Number (if known): TBD

Device Name: Trestle Luxe Anterior Cervical Plate System

Indications for Use:
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- trauma (i.e., fracture or dislocation)
- spinal stenosis
- pseudoarthrosis
- tumor
- and failed previous fusion.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The Counter Use _____

(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 K102820