



Food and Drug Administration
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Stryker Corporation
Ms. Tina Mornak
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

July 15, 2015

Re: K150700

Trade/Device Name: ACP 1™ Anterior Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 18, 2015
Received: June 19, 2015

Dear Ms. Mornak:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150700

Device Name

ACP 1™ Anterior Cervical Plating System

Indications for Use (Describe)

The ACP 1™ Anterior Cervical Plating System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation.

The ACP 1™ 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 patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Tina Mornak Regulatory Affairs Specialist Phone: 201-760-8193 Fax: 201-962-4193 E-mail: tina.mornak@stryker.com
Date Prepared	June 30, 2015
Trade Name	ACP 1™ Anterior Cervical Plating System
Common Name	Appliance, fixation, spinal intervertebral body
Proposed Class	Class II
Classification Name and Number	Spinal intervertebral body fixation orthosis 21 CFR §888.3060
Product Code	KWQ
Predicate Devices	Primary Predicate: Stryker Spine, Aviator® Anterior Cervical Plating (ACP) System, K142237 Additional Predicates: Synthes Anterior CSLP System, K000742 BioMet MaxAn® Anterior Cervical Plate System, K133518
Device Description	<p>The ACP 1™ Anterior Cervical Plating System are one-, two-, three- and four-level plate configurations ranging in lengths 10mm to 22mm for the one-level plates, 24mm to 46mm for the two-level plates, 39mm to 69mm for the three-level plates and 56mm to 96mm for the four-level plates. A locking screw is utilized as an anti-backout mechanism to lock the bone screws in place. The bone screws are provided with either fixed or variable angles available in self-tapping or self-drilling designs. The variable angle bone screws allow the screw to be placed into bone at various degrees of angulation, while the fixed bone screws are inserted at a defined angle. Any combination of bone screws can be used to secure the cervical plate. The bone screws are offered in 4.0mm and 4.5mm diameters in lengths 10mm - 20mm. The implants (bone screws and cervical plates) are provided as single-use, sterile devices manufactured from titanium alloy (Ti6Al4V) per ASTM F136 and ISO 5832-3, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies.</p> <p>The associated instrumentation are Class I / 510(k) exempt devices under 21 CFR §888.4540.</p>
Indications for Use	<p>The ACP 1™ Anterior Cervical Plating System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation.</p> <p>The ACP 1™ 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:</p> <ul style="list-style-type: none"> • Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Trauma (including fractures) • Tumors • Deformities or curvatures (including kyphosis, lordosis, or scoliosis) • Pseudarthrosis

510(k) Summary	
	<ul style="list-style-type: none"> • Failed previous fusion • Decompression of the spinal cord following total or partial cervical vertebrectomy • Spondylolisthesis • Spinal stenosis
Summary of the Technological Characteristics	<p>The purpose of this Traditional 510(k) is to summarize the design changes and sterile labeling that have been implemented to the Aviator® Anterior Cervical Plating (ACP) System. These modifications did not alter the fundamental scientific technology or change/introduce an energy source. The modified devices retained by previously FDA cleared indications/intended use and mode of operation as presented in 510(k) #K142237.</p> <p>The ACP 1™ System introduces a locking screw as an anti-backout mechanism. The primary screw locking mechanism is a locking screw, which is designed to lock over the bone screw heads. Insertion of the locking screw locks the bone screws in place and allows for additional visual and tactile feedback that the bone screws are locked. The ACP 1™ System will be provided sterile to the end-user. The implants continue to be manufactured from surgical grade implantable titanium alloy.</p> <p>The implemented modifications did not raise new questions of safety or efficacy.</p>
Summary of the Performance Data	<p>Risk analysis was performed to demonstrate that the ACP 1™ System is substantially equivalent to its predicate devices. The risk analysis determined that the predefined acceptance criteria associated with the following mechanical testing was met:</p> <ul style="list-style-type: none"> • Static and dynamic compression testing per ASTM F1717-14 • Static torsion testing per ASTM F1717-14
Conclusions	<p>The ACP 1™ System has identical indications, technological characteristics, and principles of operation as its predicates. The risk analysis performed demonstrates that any minor differences do not impact device performance as compared to the predicates. The ACP 1™ System was shown to be substantially equivalent to its predicate devices.</p>