

APR 01 2014**510(k) Summary**

Proprietary Name: VariAx Clavicle Hook Plate

Common Name: Plate, Fixation, Bone

Classification Name and Reference: Single/multiple component metallic bone fixation appliances and accessories
21 CFR §888.3030

Smooth or threaded metallic bone fixation fastener
21 CFR §888.3040

Device Class: Class II

Product Code(s): HRS & HWC

Sponsor: Stryker Trauma AG

For Information Contact: Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430
Phone: 201-831-5691
Fax: 201-831-4691

Date Prepared: January 31, 2014

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market a line extension to the VariAx Clavicle System, which was previously cleared in VariAx Clavicle System (K113760 & K130116). The VariAx Clavicle System consists of anatomically contoured, Anterior and Superior Lateral Plates as well as Anterior and Superior Midshaft Plates. The subject plates are fixed to the clavicle using 3.5mm or 2.7mm locking or non-locking screws. These screws were cleared in K073527, K101056 and K132502. This 510(k) submission is intended to introduce Hook Plates to the currently marketed VariAx Clavicle System. The plates are manufactured from Titanium Alloy per ASTM F136 (plate) and Commercially Pure Titanium per ASTM F67 (screw holes).

Intended Use

Intended for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions, and dislocations of the acromioclavicular joint.

Indications for Use

Intended for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions, and dislocations of the acromioclavicular joint.

Substantial Equivalence

The subject VariAx Clavicle Hook Plate is substantially equivalent to the VariAx Clavicle System (K113760 & K130116), AAP AcroPlate (K030909) and Synthes (USA) Clavicle Hook Plates (K061753) in regards to intended use, design, materials, and operational principles for use for use in internal fixation in the clavicle.

Non-Clinical Testing

Non-clinical laboratory testing was performed for the VariAx Clavicle Hook Plate components to determine substantial equivalent. Testing demonstrated that the VariAx Clavicle Plate System is substantially equivalent to the predicate devices. A Finite Element Analysis (FEA) was conducted on the subject VariAx Clavicle Hook Plate in order to assess the worst case plate for performance verification testing. In addition to this, fatigue testing was also conducted to compare the fatigue properties of the subject plates to the predicate AAP AcroPlate. The aim of the testing was to demonstrate substantial equivalence between the subject VariAx Clavicle Hook plate and the predicate AAP AcroPlate.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject components of the VariAx Clavicle Hook Plate are substantially equivalent to the predicate devices identified throughout this submission.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 1, 2014

Stryker Trauma AG
Mr. Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K140259

Trade/Device Name: VariAx Clavicle Hook Plate

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: February 12, 2014

Received: February 14, 2014

Dear Mr. Wreh:

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

Page 2 – Mr. Elijah N. Wreh

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 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>. 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,

Lori A. Wiggins

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

Enclosure

