MAR 0 5 2013

K130116

510(k) Summary

Proprietary Name:	Variax Clavicle System
Common Name:	Plate, Fixation, Bone
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR § 888.3030
Proposed Regulatory Class:	Class II
Product Codes:	HRS, HWC
Predicate Devices:	Variax Clavicle
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Person:	Estela Celi Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3461 estela.celi@stryker.com
Date Prepared:	January 15,2013

Device Description

The Variax Clavicle System consists of anatomically contoured Anterior and Superior Lateral Plates as well as Anterior and Superior Midshaft Plates which were previously cleared in K113760. The plates are manufactured from Titanium alloy per ASTM F136 and Commercially Pure Titanium per ASTM F 67. The plates are fixed to the clavicle using 3.5mm or 2.7mm locking or non-locking screws. This Special 510(k) submission is intended to introduce 145mm Superior Lateral Plates as a line extension to the currently marketed Superior Lateral Plates in the Variax Clavicle System. This will extend the range of plate sizes from 74mm-145mm in length.

Intended Use

The Variax Clavicle System is intended for use in internal fixation in the clavicle.

Indications for Use

The Variax Clavicle System Anterior/Superior Lateral and Anterior/Superior Midshaft Plates are indicated for fixation of single, segmental and comminuted fractures, osteotomies, mal-unions, and non-unions of the clavicle.

Substantial Equivalence

The subject Superior Lateral Plates are substantially equivalent to the Superior Lateral Plates in the Variax Clavicle System cleared under K113760 in regards to intended use, design, materials, and operational principles as a bone fixation device.

Non-Clinical Testing

Risk analysis was performed according to the requirements of ISO 14971:2007 "Medical Devices-Application of risk management to medical devices." Records of the risk analysis process are retained in the design history file. This evaluation demonstrated that the new plate length did not present a new worst case and that the same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate (K113760) The analysis demonstrated that the subject Variax Clavicle System plates met performance requirements and are as safe and effective as their predicate devices.

Conclusion

The subject components of the Variax Clavicle System are substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Stryker Trauma AG
% Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Letter dated: March 5, 2013

Re: K130116
Trade/Device Name: Variax Clavicle System
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 4, 2013
Received: February 5, 2013

Dear Ms. Celi:

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 -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): K130116

Device Name: Variax Clavicle System

The Variax Clavicle Anterior/Superior Lateral and Anterior/Superior Midshaft Plates are indicated for fixation of single, segmental and comminuted fractures, osteotomies, mal-unions, and non-unions of the clavicle.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices