

K140565

510(k) Summary

Proprietary Name: VariAx 2 Compression Plating System

Common Name: Bone plates
Bone Screws

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

Regulatory Class: Class II

Product Codes: 87 HRS: Plate, Fixation, Bone
87 HWC : Screw, Fixation, Bone

Sponsor: Stryker Trauma AG
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Switzerland

Contact Person: Estela Celi
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Date Prepared: March 3, 2014

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the modified VariAx 2 compression plate of the VariAx 2 Compression Plating System, previously cleared in K130009. The VariAx 2 Compression Plating System is an internal fixation device that consists of various plates used with compatible screws to fit different types of fractures in the radius, ulna, humerus, clavicle, distal tibia and fibula. The subject components will be available sterile and non-sterile. The plates will be available in sizes ranging from 30-246mm in length.

Intended Use

The Stryker VariAx 2 Compression Plating System is intended for internal fixation of bones in adult patients.

Indications

The Stryker VariAx 2 Compression Plating System is indicated for internal fixation of fractures in the Radius, Ulna, Humerus, Clavicle, Distal tibia and Fibula for the following indications:

- osteotomies, mal-unions, and non-unions
- single, segmental, and comminuted fractures
- normal bone density and osteopenic bone

Summary of Technologies

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate device:

- K130009 VariAx 2 Compression Plating System

Non-Clinical Testing

Non-clinical laboratory testing was performed for the VariAx 2 Compression Plating System modified plates to determine substantial equivalence. Testing demonstrated that the modified plates are substantially equivalent to the previously cleared K130009.

The following testing was performed

- Compression Plates Screw Through Compression Hole 0° and 15° Angulation with VariAx Screws

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The VariAx 2 Compression Plating System is substantially equivalent to the predicate device identified in this premarket notification.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO60-C1609
Silver Spring, MD 20993-0002

May 29, 2014

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

Re: K140565

Trade/Device Name: VariAx 2 Compression Plating 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: March 3, 2014
Received: March 5, 2014

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

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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" (21 CFR 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,

Lori A. Wiggins

for

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): K140565

Device Name: VariAx 2 Compression Plating System

Indications for Use:

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- single, segmental, and comminuted fractures
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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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