



Food and Drug Administration
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August 7, 2014

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

Re: K141992
Trade/Device Name: VariAx 2 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: July 21, 2014
Received: July 22, 2014

Dear Ms. Estela 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 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K141992

Device Name

VariAx 2 System

Indications for Use (Describe)

The Stryker VariAx 2 System is intended for use in internal fixation, reconstruction and treatment of fractures in the foot and ankle in adult and adolescent (12-21 years) patients.

Including:

- Replantation
- Joint fusions
- Corrective osteotomies
- Osteopenic bone

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth L. Frank -S

Division of Orthopedic Devices

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510(k) Summary

Proprietary Name: VariAx 2 System

Common Name: Bone plates and 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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Date Prepared: July 21, 2014

Device Description

This Special 510(k) submission is being supplied to the U.S. FDA seeking clearance for additional compatibility between the previously cleared VariAx 2 System (K140376) and previously cleared VariAx 2 System screws (K132502 and K140769). The previously cleared screws include the T8 Ø2.4mm, T10/T8 Ø2.7mm, and T10 Ø3.5mm screws. The VariAx 2 System is an internal fixation device that consists of various plates used with compatible screws to fit different types of fractures and corrective procedures in the foot and ankle.

Intended Use

The Stryker VariAx 2 System is intended for use in internal fixation, reconstruction and treatment of fractures in the foot and ankle in adult and adolescent (12-21 years) patients.

Indications

The Stryker VariAx 2 System is intended for use in internal fixation, reconstruction and treatment of fractures in the foot and ankle in adult and adolescent (12-21 years) patients.

Including:

- Replantation
- Joint fusions
- Corrective osteotomies
- Osteopenic bone

Substantial Equivalence

The subject device components are substantially equivalent to the previously cleared VariAx 2 System (K140376) in regards to intended use, materials, and operational principles and similar with regard to design for use for internal bone fixation in adult patients.

Non-Clinical Testing

A risk analysis was performed according to the requirements of ISO 14971: “Medical Devices – Application of risk management of medical devices.” Records of the risk analysis process are retained in the design history file. The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject components in comparison to the previously cleared predicate device (K140376). The analyses demonstrated that the subject components met the performance requirements and are as safe and effective as the predicate device.

Conclusion

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