

Proprietary Name: VariAx 2 System **APR 17 2014**

Common Name: 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: HRS: Plate, Fixation, Bone  
HWC: Screw, Fixation, Bone  
HTN: Washer, Bolt Nut

Sponsor: Stryker Trauma AG  
Bohnackerweg 1  
CH-2545 Selzach  
Switzerland

Contact Person: Elijah N. Wreh  
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Date Prepared: March 26, 2014

**Description**

This Special 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the VariAx 2 System. The VariAx 2 System is an internal fixation device consisting of screws and instrumentation that will be used in conjunction with previously cleared VariAx Plating Systems to treat a number of different types of fractures in the radius, ulna, humerus, clavicle, foot, ankle, distal tibia and fibula. These screws can be used in conjunction with said plating systems, or in the case of non-locking screws, may also be used independently using a lag screw technique. The subject components will be available sterile and non-sterile.

***Intended Use***

The Stryker VariAx 2 System is intended for internal bone fixation in adult patients.

***Indications***

The Stryker VariAx 2 System screws, when used in conjunction with VariAx Plating Systems; or used independently in a lag screw technique, are indicated for:

- Internal fracture fixation;
- Osteotomies;
- Revision procedures such as non-unions or mal-unions;

In addition, the following indications are specific to the devices listed below:

- T8 2.4mm Screws & T8 2.0mm Locking Peg: For use in small bones, primarily including the Distal Radius, in the treatment of:
  - Compression fractures;
  - Intra-articular and extra-articular fractures;
  - Displaced fractures;
  - Reconstruction procedures;
- T8 2.7mm Screws: For use in small bones, including the Distal Radius as well as the fore, mid- and hind Foot and Ankle, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Radius,
  - Displaced and compression fractures of the Distal Radius;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Reconstruction procedures in the Foot & Ankle and Distal Radius;
- T10 3.5mm and T10 2.7mm Screws: For use in the Radius, Ulna, Clavicle, Humerus, Foot and Ankle, Distal Tibia and Fibula, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
  - Single, segmental and comminuted fractures;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Normal bone density or osteopenic bone.

***Substantial Equivalency***

The subject device components are substantially equivalent to the previously cleared VariAx 2 System (K132502) in regards to intended use, materials, and operational principles and similar with regard to design for use in for internal bone fixation in adult patients.

***Non-Clinical Test***

A risk analysis was performed according to the requirements of ISO 14971: "Medical Devices – Application of risk management of medical devices." 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 (K132502). The analyses demonstrated that the subject components met the performance requirements and are as safe and effective as the predicate devices.

***Conclusion***

The subject components of the VariAx 2 System are substantially equivalent to the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WC066-G609  
Silver Spring, MD 20993-0002

April 17, 2014

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

Re: K140769

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, HTN

Dated: March 26, 2014

Received: March 27, 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

**Indications for Use**510(k) Number (if known):     K140769    

Device Name: VariAx 2 System

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  - Displaced fractures;
  - Reconstruction procedures;
- T8 2.7mm Screws: For use in small bones, including the Distal Radius as well as the fore, mid- and hind Foot and Ankle, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Radius,
  - Displaced and compression fractures of the Distal Radius;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
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- T10 3.5mm and T10 2.7mm Screws: For use in the Radius, Ulna, Clavicle, Humerus, Foot and Ankle, Distal Tibia and Fibula, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
  - Single, segmental and comminuted fractures;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Normal bone density or osteopenic bone.

Prescription Use     X      
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Elizabeth L. Frank-S**

Divison of Orthopedic Devices