



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Stryker GmbH  
Kurdea Lyon  
Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07423

October 27, 2015

Re: K151769

Trade/Device Name: Anchorage 2 CP 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: September 24, 2015

Received: September 25, 2015

Dear Kurdea Lyon:

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 Parts 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 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,

**Mark N. Melkerson -S**

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) K151769 (page 1 of 1)

Device Name  
Anchorage 2 CP System

**Indications for Use (Describe)**

The Stryker Anchorage 2 CP 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 include:**

- 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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

**Submitter:** Stryker GmbH  
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Switzerland

**Contact Person:** Kurdea Lyon  
Regulatory Affairs Specialist  
Phone: (201) 831-5996  
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**Name of Device:** Anchorage 2 CP System

**Common Name:** Bone Plates  
Bone Screws

**Classification Name:** 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

**Predicate Devices:** Stryker Foot Plating System- K063875  
VariAx 2 System- K141992

**Reference device:** VariAx 2 System (partially threaded Ø2.7mm VariAx 2 screw) - K132502

**Date Prepared:** June 29, 2015

**Device Description**

This Traditional 510(k) submission is being supplied to the U.S. FDA to seek clearance to market the new Anchorage 2 CP System. The Anchorage 2 CP System is an internal fixation device that consists of various plates used with compatible screws to treat different types of corrective osteotomies and fractures in the foot and ankle. The subject plates comprise of a new countersunk screw interface that is only compatible with the new inter-fragmentary partially threaded Cross-Plate (CP) lag screws. The subject components will be available sterile and non-

sterile. The plates will be available in sizes ranging from 23-49mm in length. The Anchorage 2 CP System is introducing Ø3.6mm and Ø4.1mm inter-fragmentary partially threaded Cross-Plate (CP) lag screws. The Anchorage 2 CP Ø3.6mm CP lag screws will be available in sizes ranging from 20-44mm in length and the Anchorage 2 CP Ø4.1mm CP lag screws will be available in sizes ranging from 20-70mm. The Anchorage 2 CP System includes holes that are only compatible with the existing VariAx 2 System screws that were previously cleared in the VariAx 2 System (K132502).

Apart from the CP Lag screws, the associated accessories include:

- CP Reamer
- CP Drill Guide for T8 Ø3.6mm CP lag screws
- CP Drill Guide for T10 Ø4.1mm CP lag screws
- CP Templates

### **Intended Use**

The Stryker Anchorage 2 CP 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 for Use:**

The Stryker Anchorage 2 CP 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 include:

- Replantation
- Joint fusions
- Corrective osteotomies
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### **Comparison of Technological characteristics with the Predicate Device:**

The device comparison showed that the subject device is substantially equivalent in intended use, design and operational principles to the previously cleared Stryker Foot Plating System (K063875) and the VariAx 2 Systems (K141992 and K132502). The subject devices are substantially equivalent to the predicate devices in regards to design, materials, and operational principles for use in internal fixation, reconstruction, and treatment of fractures in the foot and ankle.

**Performance Data:****Non-clinical Testing**

Biomechanical testing was performed on the Anchorage 2 CP System components to determine substantial equivalence. Testing demonstrated that the Anchorage 2 CP System is substantially equivalent to the predicate devices currently cleared for marketing.

The following tests were performed:

- Construct Fatigue Strength Testing as per ASTM F382-14 (Plates and CP Screws)
- Insertion Torque Testing as per ASTM F543-13 (CP Screws)
- Shear-off Testing as per ASTM F543-13(CP Screws)
- Pull-out Testing as per ASTM F543-13(CP Screws)

**Biocompatibility Testing**

The biocompatibility evaluation for the Stryker Anchorage 2 CP System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993-1. “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The screws are categorized as per EN ISO 10993-1:2009 (E) as “Implant Device” with “Tissue/bone” contact duration > 30 days. The material is Titanium alloy (Ti6Al4V-ELI) as per ASTM F136. The plates are categorized as per EN ISO 10993-1:2009 (E) as “Implant Device” with “Tissue/bone” contact duration > 30 days. The material is commercially pure Ti as per ASTM F67. All Class II instruments are categorized as per EN ISO 10993-1: 2009 (E) as an “instrument” with “Tissue/bone” contact of duration <24 hours.

**Animal Testing**

Animal testing was not required for this submission.

**Clinical Testing**

Clinical testing was not required for this submission.

**Conclusion**

The subject device has the same intended use and similar technological characteristics as the predicate devices. The non-clinical laboratory data support the safety of the subject Anchorage 2 CP System and demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the subject Anchorage 2 CP system is substantially equivalent to the predicate devices identified throughout this submission.