510(k) Summary

Proprietary Name:	AxSOS 3 Ti Locking Plate System	JUN 2 0 2014
Common Name:	Bone Plates Bone Screws	
Classification Name and Reference:	Single/multiple component metallic bone fixation appliance 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	
Sponsor:	Stryker Trauma AG	
Contact Person:	Elijah N. Wreh Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 elijah.wreh@stryker.com Phone: 201-831-5691 Fax: 201-831-4691	
Date Prepared:	April 29, 2014	

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to obtain authorization to market additional plates and screws within the AxSOS 3 Ti Locking Plate System. The AxSOS 3 Ti Locking Plate System includes anatomically contoured monoaxial locking plates. The 5.0mm System consists of the Distal Lateral Femur Plate (K123964). The 4.0mm System comprises the Proximal Lateral Tibia Plate (K123964) as well as the subject devices being the Distal Anterolateral Tibia Plate, the Distal Medial Tibia Plate and the Proximal Medial Tibia Plate. The system includes four (4) types of screws available in various diameter and thread length: locking, cortical, cancellous (K123964 & K133440) as well as the subject periprosthetic screws. The plates have been designed with holes that can accommodate either a locking or non-locking screw both at the peri-articular end and along the shaft of the plate. The plates also have an

oblong hole located at the metaphyseal junction used to aid in positioning. The subject components will be available sterile and non-sterile.

Intended Use
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.

Indications for Use
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.
Indications include:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies
- Periprosthetic fractures of the femur and proximal tibia

Summary of Technology
The device comparison showed that the subject device is substantially equivalent in intended use, design, materials and operational principles to the following predicate devices:

- Synthes LCP Distal Tibia Plates (K013248)
- Synthes (USA) 3.5/4.5MM LCP Medial Proximal Tibia Plates (K050646)
- Peri-Loc Bone Plating and Screw System (K083032)
- Synthes Peri-Prosthetic Screws (K041533)

The subject plates and screws are substantially equivalent to the predicate devices in regards to intended use, design, materials, and operational principles for use for long bone fracture fixation.

Non-Clinical Test
Non-clinical laboratory testing was performed on the worst case subject plates to determine substantial equivalence. The following testing was performed:

- "*Standard Specification and Test Method for Metallic Bone Plates*" as per ASTM F382-99 (reapproved 2008)
- "*Standard Specification and Test Methods for Metallic Medical Bone Screws* as per ASTM F 543-07"

Testing demonstrated that the subject plates are substantially equivalent to the currently marketed predicate devices.

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The subject AxSOS 3 Ti Locking Plate System is substantially equivalent to the predicate devices identified throughout this submission.

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
Mr. Elijah Wreh
Regulatory Affair Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

June 20, 2014

Re: K141121
Trade/Device Name: AxSOS 3 Ti Locking Plate 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: April 29, 2014
Received: May 01, 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 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 -A

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)*
K141121

Device Name
AxSOS 3 Ti Locking Plate System

Indications for Use *(Describe)*
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.
Indications include:
- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies
- Periprosthetic fractures of the femur and proximal tibia

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 D. Frank -S

Division of Orthopedic Devices

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

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