DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 26, 2016

Stryker GmbH
Saad Attiyah
Senior Regulatory Affairs Manager
Bohnackerweg 1
2545 Selzach, CH 2545
SWITZERLAND

Re: K153379
Trade/Device Name: AxSOS 3 Ti
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 25, 2016
Received: April 26, 2016

Dear Saad Attiyah:

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)*
K153379

Device Name
AxSOS 3 Ti

Indications for Use *(Describe)*

AxSOS 3 Ti 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

The AxSOS 3 Ti Waisted Compression Plates are also indicated for fracture fixation of:

- Periprosthetic fractures
- Diaphyseal and metaphyseal areas of long bones in pediatric patients.

The 4mm Waisted Compression Plate indications also include fixation of the scapula and the pelvis.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 7. 510(k) Summary

Submitter:	Stryker GmbH Bohnackerweg 1 2545 Selzach Switzerland
Contact Person:	Saad Attiyah Senior Regulatory Affairs Manager Phone: 201-831-5655 Fax: 201-831-4691
Establishment Number	8031020
Date Prepared:	May 24, 2016
Name of Device:	AxSOS 3 Ti
Common or Usual Name	Bone Plates Bone Screws
Classification Name:	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:	II
Product Codes:	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bone
Predicate Device:	AxSOS 3 Ti Locking Plate System (K141121) AxSOS 3 Ti Locking Plate System (K143138) OrthoHelix Surgical Design (K113048, K122005, K132591)
Reference Device:	Zimmer NCB Blind Screw Insert (K113718)

Intended Use:

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

Indications for Use:

AxSOS 3 Ti 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

The AxSOS 3 Ti Waisted Compression Plates are also indicated for fracture fixation of:

• Periprosthetic fractures
• Diaphyseal and metaphyseal areas of long bones in pediatric patients.

The 4mm Waisted Compression Plate indications also include fixation of the scapula and the pelvis.

Description:

The AxSOS 3 Ti Plating System consists of various monoaxial plates and screws made from Ti-6Al-4V (ASTM F-136 ELI). The system contains previously cleared distal lateral femur plates, proximal lateral tibial plates, distal anterolateral tibia plates, distal medial plates, proximal medial tibia plates and proximal humerus plates provided in various lengths (K123964, K133440, K141121, and K143138). This premarket notification introduces 4.0 mm waisted compression plates and 5.0 mm broad

	and narrow waisted compression plates in various lengths and number of holes. The system contains previously cleared screws with various lengths and diameters and provided in various configurations (fully or partially threaded) identified in previously cleared premarket notifications (K123964, K133440, K141121, and K143138). This premarket notification introduces blind screws used with the 4.0 mm and 5.0 mm waisted compression plates.
Bench Testing:	An engineering analysis was performed comparing the specific predicate devices.
Animal Testing:	Animal testing was not required for this submission.
Clinical Testing:	Clinical testing was not required for this submission.
Substantial Equivalence Statement:	Documentation is provided which demonstrates that the AxSOS 3 Ti is substantially equivalent to its predicate and reference devices in terms of its material, design, and indications for use, and performance characteristics.