Stryker GmbH
Kemine Hale
Sr. Regulatory Affairs Specialist
Bohnackerweg 1
Selzach, 2545
Switzerland

December 15, 2017

Re: K172350
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: November 10, 2017
Received: November 13, 2017

Dear Kemine Hale:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K172350

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.

510(k) Summary

Proprietary Name:	AxSOS 3 Ti
Common Name:	Bone Plates Bone Screws
Regulation Number & Regulation Description:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Product Code:	HRS (Plate, Fixation, bone) HWC (Screw, Fixation, Bone/Washer)
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Kemine Hale Sr. Regulatory Affairs Specialist Bohnackerweg 1 2545 Selzach, Switzerland kemine.hale@stryker.com Phone: +41 32 641 6935
Date Prepared:	December 14, 2017
Primary Predicate:	AxSOS 3 Ti (K153379 & K162439)
Reference Devices:	Dall-Miles Homogenous Vitallium Cable (K961283) Fixos Screw System (K133451) Asnis III Cannulated Screw System (K000080)

Description

This traditional 510(k) submission is intended to update the labeling of the AxSOS 3 Ti system to include MR compatibility and to introduce an additional component, the AxSOS 3 Ti 5.0mm Cable Plug. The AxSOS 3 Ti system was previously cleared in K153379 and K162439.

The AxSOS 3 Ti system (also referred to as the AxSOS 3 Ti Locking Plate system) is a system used for internal fixation applications. The system includes anatomically contoured monoaxial locking plates, as well as screws and blind screws (limited to waisted compression plates) . The plates have been designed with holes that can accommodate either locking or non-locking screws, and also include holes for suture and Kirschner wires (K-wires). The screws come in 3 types (locking, cortical, and cancellous) and are available in several different diameters. All implantable components are available sterile and non-sterile and are manufactured from titanium alloy (Ti6Al4V-ELI) per ASTM F136.

The AxSOS 3 Ti 5.0mm Cable Plug is categorized as permanent, direct bone/tissue patient contacting implant with contact duration >30 days. It is manufactured from titanium alloy (ASTM F136, Ti6Al4V-ELI) and is Type II anodized. It is designed to be used in combination with the 5.0mm AxSOS 3 Ti system. It is an aid for internal fixation component used in conjunction with the AxSOS 3 Ti 5.0mm distal lateral femur, broad compression and narrow compression plates. The Cable Plug is threaded or clicked into a 5.0mm universal locking hole of the AxSOS 3 Ti plates and provides a positioning point for a cerclage cable.

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.

Summary of Technologies

A comparison of the systems demonstrated the subject AxSOS 3 Ti system is substantially equivalent to the previously cleared AxSOS 3 Ti system (K162439) and the Dall-Miles Homogenous Vitallium Cable (K961283) with regards to intended use, material, design and operational principles.

Non-Clinical Testing

Testing was performed to ASTM F543-13 – Pull Out Test and ASTM STP 731-Dynamic Compression Test for the Cable Plug component.

Testing was performed to determine the compatibility of the system in a MR environment. These tests included an assessment of:

- Magnetically Induced Displacement Force per ASTM F2052
- Magnetically Induced Torque per ASTM F2213
- Heating by RF Fields per ASTM F2182
- Image Artifacts per ASTM F2119

Testing demonstrated that the subject device is substantially equivalent to the marketed predicate device.

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The AxSOS 3 Ti system described in this submission is identical to the previously cleared predicate, K153379, K162439 and K961283, with the exception of the additional component. Non-clinical testing has been used to support substantial equivalence. The testing demonstrated that the subject system performs as intended and at least as well as the predicate. Based on these attributes the subject AxSOS 3 Ti is substantially equivalent to the Stryker GmbH AxSOS 3 Ti system and the Dall-Miles Homogenous Vitallium Cable.