June 5, 2020

Stryker GmbH
Paul Nelson
Staff Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K200398
Trade/Device Name: AxSOS 3 AF System and AxSOS 3 Ti 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: May 22, 2020
Received: May 27, 2020

Dear Paul Nelson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200398

Device Name
AxSOS 3 AF System

Indications for Use *(Describe)*
The AxSOS 3 Ankle Fusion System is indicated for arthrodesis of the ankle, which includes tibio-talo-calcaneal, tibio-talar, and tibio-calcaneal arthrodesis, in possible conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200398

Device Name
AxSOS 3 Ti System

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.

Screws can also be used for arthrodesis.

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)

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510(k) Summary

Submitter:
Stryker GmbH
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Switzerland

Contact Person:
Paul Nelson
Staff Specialist, Regulatory Affairs
Phone: (201) 831-5691
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Date Prepared:
February 7, 2018

Name of Device:
AxSOS 3 AF System
AxSOS 3 Ti System

Common or Usual Name:
Plate, Fixation, Bone

Screw, Fixation, Bone

Classification Name:
AxSOS 3 AF System
Single/multiple component metallic bone fixation appliances and accessories
21 CFR § 888.3030 (primary)

Smooth or threaded metallic bone fixation fastener
21 CFR § 888.3040

AxSOS 3 Ti System
Single/multiple component metallic bone fixation appliances and accessories
21 CFR § 888.3030 (primary)

Smooth or threaded metallic bone fixation fastener
21 CFR § 888.3040

Regulatory Class:
Class II

Product Codes:
AxSOS 3 AF System
HRS, HWC

AxSOS 3 Ti System
HRS, HWC

Primary Predicate:
AxSOS 3 AF System
Ortholoc 3Di Ankle Fusion Plating System, K163650

AxSOS 3 Ti System
AxSOS 3 Ti System, K181091

Additional Predicate:
AxSOS 3 Ti System

Asnis III Cannulated Screw System, K024060
Stryker Locked Plating System, K050512
Monster Screw System, K190586

Description:

AxSOS 3 AF System

AxSOS 3 AF (Ankle Fusion) is an internal fixation system composed of sterile and non-sterile plates, and associated instruments. These plates are available in a variety of anatomical orientations and made of titanium alloy, with Type II anodization, and used with compatible screws.

AxSOS 3 Ti System

AxSOS 3 Ti is an internal fixation system composed of sterile and non-sterile plates, screws, and complementary, implantable devices, along with associated instruments. The plates are available in a variety of anatomical orientations and lengths. Implants of this system are available in titanium alloy, with Type II anodization.

Indications for Use:

AxSOS 3 AF System

The AxSOS 3 Ankle Fusion System is indicated for arthrodesis of the ankle, which includes tibio-talo-calcaneal, tibio-talar, and tibio-calcaneal arthrodesis, in possible conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

AxSOS 3 Ti System

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.

Screws can also be used for arthrodesis.

Summary of Technologies:

A comparison of systems demonstrated that the subject AxSOS 3 AF and AxSOS 3 Ti systems are substantially equivalent to the previously cleared, predicate systems mentioned above when considering intended use, material, design, and operating principles.

The subject and predicate devices for both AxSOS 3 AF and AxSOS 3 Ti systems utilize the same general technological and design characteristics found in plate and screw device types to achieve the same intended use of bony tissue fixation. In addition, where applicable, these devices contain geometries allowing for a screw locking mechanism. Among these systems is also the use of titanium alloy.

The subject and predicate devices for both AxSOS 3 AF and AxSOS 3 Ti systems do differ on specific design feature geometries and dimensions. Performance testing established that these differences do not hinder subject devices from performing at least as well as the predicates, thus demonstrating that the subject devices are safe and effective.

Performance Data:

Non-Clinical Testing

Comparative, mechanical testing to predicate devices demonstrated substantial equivalence:

Screws were tested per ASTM F543

- Pull-Out
- Torsional Strength
- Insertion Torque

Screw-plate constructs were tested using axial compression bending fatigue.

Tests performed to establish compatibility with a magnetic resonance environment:

- Induced Displacement
- Induced Torque
- RF Heating
- Image Artifacts

Clinical Testing

Clinical testing was not a requirement for this submission.

Conclusion:

The AxSOS 3 AF and AxSOS 3 Ti subject systems have similar indications, intended use, target populations, technological characteristics, and materials as the predicate devices. Mechanical testing demonstrated the performance of the proposed devices is equivalent to the predicate devices.