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

February 3, 2017

Stryker GmbH
Irene Bacalocostantis
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K162439
Trade/Device Name: AxSOS 3 Ti; Stryker Plating 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: January 4, 2017
Received: January 5, 2017

Dear Irene Bacalocostantis:

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" (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.

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,

Vincent J. Devlin -S

for

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)*
K162439 (page 1 of 2)

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.

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

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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)*
K162439 (page 2 of 2)

Device Name
Stryker Plating System

Indications for Use *(Describe)*
SPS Small Fragment Set The Stryker® Plating System,
Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

- One third tubular plate: fibula, metatarsals, metacarpals
- Fibular plate: fibula
- Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
- Oblique T-plate: distal radius
- T-plate: distal radius, calcaneus, lateral clavicle
- Cloverleaf plate: proximal humerus, distal tibia
- Calcaneal plate: calcaneus
- Reconstructive plate: humerus, pelvis Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set The Basic Fragment Set is intended for use in long bone fracture fixation. Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

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

Proprietary Name:	AxSOS 3 Ti Stryker Plating System
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:	Irene Bacalocostantis Ph.D. Sr. Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6797
Date Prepared:	February 2, 2017
Predicate Devices:	AxSOS 3 Ti (K153379) Stryker Plating System (K060798)

Description

The AxSOS 3 Ti system includes anatomically contoured monoaxial locking plates, as well as screws and blind screws. The plates have been designed with holes that can accommodate either locking or non-locking screws, and also include holes for suture and Kirshner wires (K-wires). The screws come in 3 types (locking, cortical, and cancellous) and are available in several different diameters. All implantable components come sterile and non-sterile.

The Basic Fragment Set is part of the Stryker Plating System. The Basic Fragment Set consists of plates and screws for fixation of fractures of the cortical and metaphyseal area of the long bone as well as fracture of the pelvis. The implant set is available in either in stainless steel (316 L) or titanium alloy (Ti6Al4V).

This submission is not intended to introduce any new implants into the system, but rather to demonstrate compatibility between the AxSOS 3 Ti system (K153379) and several of the titanium screw/plate components found in the Stryker Plating System (SPS) most recently cleared in K060798. The AxSOS 3 Ti plates and screws are manufactured from titanium alloy (Ti6Al4V) per ASTM F136 and available sterile and non-sterile.

AxSOS 3 Ti

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.

Stryker Plating System

Indications for Use:

SPS Small Fragment Set The Stryker® Plating System,
Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

- One third tubular plate: fibula, metatarsals, metacarpals
- Fibular plate: fibula
- Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
- Oblique T-plate: distal radius
- T-plate: distal radius, calcaneus, lateral clavicle
- Cloverleaf plate: proximal humerus, distal tibia
- Calcaneal plate: calcaneus
- Reconstructive plate: humerus, pelvis Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set The Basic Fragment Set is intended for use in long bone fracture fixation. Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Summary of Technologies

There are no changes to the design or technological characteristics of the AxSOS 3 Ti system implants, nor in the Stryker Plating System.

Non-Clinical Testing

Bench testing and an engineering analysis were provided to demonstrate compatibility between components.

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an Endotoxin limit of ‹ 20EU/Device.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

There have not been any changes or component additions to the AxSOS 3 Ti system. A bench testing and engineering analysis show that several of the plate and screw components in the AxSOS 3 Ti and Stryker Plating System are cross-compatible. The cross-compatibility between the AxSOS 3 Ti System and Stryker Plating System are found in the operative technique guides.