April 27, 2023

Stryker GmbH
Danielle Madureira
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K222381
Trade/Device Name: PeriPRO™ Femur System, Variable Angle Fixation System, AxSOS 3Ti, 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: March 31, 2023
Received: March 31, 2023

Dear Danielle Madureira:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222381

Device Name
PeriPRO™ Femur System

Indications for Use *(Describe)*

The PeriPRO™ Femur Plating System is indicated for internal fixation and stabilization of femur fractures and osteotomies in normal and osteopenic bone. This includes:

- Non-unions, malunions and deformities
- Fracture in the presence of intramedullary implants, including periprosthetic fractures

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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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
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222381

Device Name
Variable Angle Fixation System

Indications for Use *(Describe)*
The Variable Angle Fixation System is indicated for the internal fixation and stabilization of fractures and osteotomies of the femur in normal and osteopenic bone, including:

- Non-unions, malunions and deformities
- Periprosthetic fractures

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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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K222381

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 4 mm 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222381

Device Name
Stryker Plating System

Indications for Use *(Describe)*

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.

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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K222381
510(k) Summary

Proprietary Name:	PeriPRO™ Femur System Variable Angle Fixation System AxSOS 3Ti System Stryker Plating System
Common Name:	Plate, Fixation, Bone and Screw, Fixation, Bone
Regulation Description:	21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulation Number:	21 CFR 888.3040 (primary), 21 CFR 888.3030
Classification Product Code:	HRS, HWC
Device Class:	II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Danielle Jannuzzi Madureira, PhD Associate Manager Regulatory Affairs Dr. Homer Stryker Strasse, 1 CH-2545 Selzach, Switzerland Phone: +41 79 890 02 89 Fax: +41 32 641 66 60
Date:	April 27, 2023
Primary Predicate:	K200398 - AxSOS 3 Ti System, Stryker GmbH
Additional Predicate:	K192217 - NCB Plating System Distal Femur and Proximal Tibia, Zimmer GmbH K172262 - EVOS Small Fragment Plating System, Smith & Nephew, Inc. K162439 – Stryker Plating System, Stryker GmbH
Device Description:	This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the PeriPRO Femur and Variable Angle Fixation System and align labeling across the AxSOS 3 Ti and SPS System. This submission encompasses multiple systems (PeriPRO Femur, Variable Angle Fixation, AxSOS 3Ti and SPS Systems) that have similar intended use and/or will be used together during the surgical procedure. The **PeriPRO™ Femur System** consists of proximal, interprosthetic and distal femur plates. All devices in the system are provided sterile and non-sterile. The proximal femur plates range from 257 up to 371 mm in length. The interprosthetic femur plate ranges from 320 up to 420 mm in length. The distal femur plates range from 173 up to 396 mm in length. All plates are made of titanium alloy (Ti6AL4VELI) according to ASTM 136. The **Variable Angle Fixation System** consists of screws and cable plugs. All devices in the system are provided sterile and non-sterile. Screws are offered as non-locking or locking variants. The locking screws are available as Ø4 (L22-95 mm), Ø5 mm (L22-120 mm) and Ø5 mm flat tip (L10-20 mm) are made of CoCr alloy. The Cable plugs are available in a 5 mm and are made

of titanium alloy. The PeriPRO™ Femur System and Variable Angle Fixation contains Class II instruments as targeters, frame fixators, handles. Those devices are part of the targeting system and as such class II instruments. They are manufactured of either PEI/Carbon or stainless steel.

AxSOS 3 Ti System 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, the screws in a variety of diameters and lengths. Implants of this system are available in titanium alloy, with Type II anodization.

The Stryker Plating System (**SPS System)** contains the Basic Fragment Set and the Small Fragment Set. Both sets contain plates, screws, and washers available in titanium alloy (Ti-6Al4V) per ASTM F136 as well as stainless steel (316L) in sterile and non-sterile forms. SPS plates come with holes that can accommodate non-locking screws and include holes for suture or K-wires. The screws are provided in 2 types (cortical and cancellous) and are available in several different lengths and diameters.

Indications for Use:

The PeriPRO™ Femur Plating System is indicated for internal fixation and stabilization of femur fractures and osteotomies in normal and osteopenic bone. This includes:

- Non-unions, malunions and deformities
- Fracture in the presence of intramedullary implants, including periprosthetic fractures

The Variable Angle Fixation System is indicated for the internal fixation and stabilization of fractures and osteotomies of the femur in normal and osteopenic bone, including:

- Non-unions, malunions and deformities
- Periprosthetic fractures

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 4 mm Waisted Compression Plate indications also include fixation of the scapula and the pelvis. Screws can also be used for arthrodesis.

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.

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.

Comparison to Predicate Device:

A comparison of the system demonstrated that the subject PeriPRO Femur and Variable Angle Fixation System is substantially equivalent to the AxSOS 3 Ti System regarding intended use, material, design, and operational principles.

Performance Data (Nonclinical):

Non-Clinical Performance and Conclusions:
The following non-clinical laboratory testing, and performance assessments were made in support of substantial equivalence:

- Static and Dynamic Cantilever Bending per ASTM F1798 and internal guidance
- Shear-off and pull-out per ASTM F543
- Insertion per ASTM F543
- Biocompatibility per ISO 10993

Tests performed to establish compatibility with a magnetic resonance environment:

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

Clinical Performance and Conclusions:
Clinical data and conclusions were not needed for this device.

Conclusion:

PeriPRO Femur and Variable Angle Fixation System
The subject devices PeriPRO Femur and Variable Angle Fixation System is substantially equivalent to the previously cleared predicate device AxSOS 3Ti System.
AxSOS 3Ti System
The subject device AxSOS 3Ti System is substantially equivalent to the previously cleared predicate device AxSOS 3Ti System.
Stryker Plating System
The subject device Stryker Plating System equivalent to the previously cleared predicate device Stryker Plating System.

Except for the modifications described in this submission the subject devices are identical to the predicate device, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices