April 7, 2023

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

Re: K223772
Trade/Device Name: PRO Plating System, Stryker Trauma Pelvic Set (Matta)
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: December 16, 2022
Received: December 16, 2022

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, M.P.H.
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)*
K223772

Device Name
PRO Plating System

Indications for Use *(Describe)*
The PRO Plating System is indicated for:
• Fractures, non-unions, deformities and malunions of the pelvic ring and acetabulum
• Sacroiliac joint dislocations

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:

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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)*
K223772

Device Name
Stryker Trauma Pelvic Set (Matta)

Indications for Use *(Describe)*
The Stryker Trauma Pelvic Set (Matta) is indicated for:
- Fractures of the acetabulum, sacrum, illium, and entire pelvic ring;
- Revision surgery of pseudarthrosis, non-unions and mal-unions;
- Osteonomies;
- Arthrodeses;
- Sacroilic joint dislocations;
- Symphysis pubis disruptions

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.

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510(k) Summary

Proprietary Name:	PRO Plating System Trauma Pelvic Set System (Matta)
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:	December 05, 2022
Primary Predicate:	PRO Plating System K131132
Additional Predicate:	Trauma Pelvic Set System (Matta) K001614
Reference Device:	aap Bone Plates and Screw Implants K072411
Device Description:	This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the new devices of the PRO Plating System, to align indication of the existing PRO Pelvis System and the new devices and add MRI labeling to the existing PRO Pelvis System and the Trauma Pelvic Set System (Matta). This submission encompasses multiple systems (PRO Pelvis System and Trauma Pelvic Set System (Matta)) that have similar intended use and/or will be used together during the surgical procedure. The PRO Plating System (Pelvis II Implant System) is an internal fixation device that consists of different types of plates used with compatible screws to fit different types of fractures in the pelvis. All devices in the system are provided sterile and non-sterile. The Stryker Trauma Pelvic Set System (Matta) consists of plate, screw, and washer components of various sizes. All are manufactured from stainless steel (ASTM F-138/139). All devices in the system are provided sterile and non-sterile.
Indications for Use:	The PRO Plating System is indicated for: • Fractures, non-unions, deformities and malunions of the pelvic ring

and acetabulum
- Sacroiliac joint dislocations

The Stryker Trauma Pelvic Set (Matta) is indicated for:
- Fractures of the acetabulum, sacrum, illium, and entire pelvic ring;
- Revision surgery of pseudarthrosis, non-unions and mal-unions;
- Osteonomies;
- Arthrodeses;
- Sacroilic joint dislocations;
- Symphysis pubis disruptions

Comparison to Predicate Device:

A comparison of the system demonstrated that the subject PRO Plating System is substantially equivalent to the PRO Plating System, Stryker Trauma Pelvic Set (Matta) and aap Bone Plates regarding intended use, material, design, and operational principles.
A comparison of the system demonstrated that the subject Stryker Trauma Pelvic Set (Matta) is substantially equivalent to the Stryker Trauma Pelvic Set (Matta) 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:
- Single Cycle Bend and Bending Fatigue Testing per ASTM F382

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 F 2119

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

Conclusion:

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 therefore, the subject devices PRO Plating System and Stryker Trauma Pelvic Set (Matta) is substantially equivalent to the previously cleared predicate device PRO Plating System and Stryker Trauma Pelvic Set (Matta).