August 18, 2023

Stryker GmbH
Danese Joiner-Fox
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K231257
Trade/Device Name: Pangea Utility Plating System, Pangea Platform
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: July 21, 2023
Received: July 21, 2023

Dear Danese Joiner-Fox:

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)*
K231257

Device Name
Pangea Utility Plating System

Indications for Use *(Describe)*
The Pangea Utility Plating System is indicated for the internal fixation and stabilization of bone fractures, osteotomies, and arthrodesis in normal and osteopenic bone, including:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions, malunions, and deformities
- Periprosthetic fractures

The Pangea Utility Plating System is also indicated for children (2-12 years) and adolescents (12 – 21 years) for the internal fixation and stabilization of bone fractures of the diaphysis and metaphysis in which growth plates have fused or in which growth plates will not be crossed by implants.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231257

Device Name
Pangea Platform

Indications for Use *(Describe)*
The Pangea Platform is indicated for the internal fixation and stabilization of bone fractures, osteotomies, and arthrodesis in normal and osteopenic bone, including:
• Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
• Non-unions, malunions, and deformities
• Periprosthetic fractures

The Pangea Platform is also indicated for children (2-12 years) and adolescents (12 – 21 years) for the internal fixation and stabilization of bone fractures of the diaphysis and metaphysis in which growth plates have fused or in which growth plates will not be crossed by implants.

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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K231257
510(k) Summary

Proprietary Name:	Pangea ™ Utility Plating System Pangea ™ Platform
Common Name:	Plate, Fixation, Bone 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
Product Code:	HRS, HWC
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Danese Joiner-Fox Associate Manager Regulatory Affairs 325 Corporate Drive Mahwah, NJ 07430 Phone: (475) 333-4452
Date Prepared:	05/01/2023
Primary Predicate:	PeriPRO Femur and Variable Angle Fixation (K222381)
Additional Predicates:	VariAx 2 System (K180500) VariAx 2 System, VariAx 2 Mini Fragment System (K191412) VariAx 2 One-Third Tubular Plating System (K151879) Osteo BOS System (K972323) AxSOS 3 Ti System (K200398) Dall-Miles Cable System (K202016)
Description	This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the Pangea Utility Plating System and the Pangea Platform. This submission encompasses multiple systems (Pangea Utility Plating System and Pangea Platform) that have similar intended use and/or will be used together during the surgical procedure. The Pangea Utility Plating System consists of mini-, small-, and large-fragment plates manufactured from Ti6Al4V-ELI per ASTM F136. The plates range in length from 26 mm to 486

mm. The Pangea Platform consists of screws and cable plugs. The screws are offered as locking or non-locking variants. The locking screws are manufactured from CoCr and are available as Ø2.7 mm (L8 mm – 80 mm), Ø3.5 mm (L10 mm – 120mm), Ø4.0 mm (L14 mm – 95 mm), Ø5.0 mm (flat tip) (L10 mm – 20 mm), and Ø5.0 mm (L14 mm – 120 mm). The non-locking screw is manufactured from Titanium alloy (Ti6Al4V-ELI per ASTM F136) and is available in Ø2.7 mm (L6 mm – 80 mm). The cable plugs are made of Titanium alloy (Ti6Al4V-ELI per ASTM F136), and the T15 and T20 cable plugs are available for the 3.5mm locking mechanism. The Cancellous screws are available as Ø4.0 mm fully and partially threaded (L10-100 mm) and Ø6 mm 16mm thread (L30 -150 mm), Ø6 mm 32mm thread (L45 -150 mm) and fully threaded (L20-150 mm).

Indications for Use

Pangea Utility Plating System

The Pangea Utility Plating System is indicated for the internal fixation and stabilization of bone fractures, osteotomies, and arthrodesis in normal and osteopenic bone, including:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions, malunions, and deformities
- Periprosthetic fractures

The Pangea Utility Plating System is also indicated for children (2-12 years) and adolescents (12 – 21 years) for the internal fixation and stabilization of bone fractures of the diaphysis and metaphysis in which growth plates have fused or in which growth plates will not be crossed by implants.

Pangea Platform

The Pangea Platform is indicated for the internal fixation and stabilization of bone fractures, osteotomies, and arthrodesis in normal and osteopenic bone, including:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions, malunions, and deformities
- Periprosthetic fractures

The Pangea Platform is also indicated for children (2-12 years) and adolescents (12 – 21 years) for the internal fixation and stabilization of bone fractures of the diaphysis and metaphysis in which growth plates have fused or in which growth plates will not be crossed by implants.

Summary of Technologies

A comparison of the systems demonstrated that the subject Pangea Utility Plating System and Pangea Platform is substantially equivalent to the PeriPRO Femur and Variable Angle Fixation (K222381) with regard to intended use, material, design, and operational principles.

Non-Clinical Testing:

The following non-clinical laboratory testing and performance assessments were made in support of substantial equivalence:

- Determination of Utility Plate worst-case constructs
- Utility Plate cross-sectional and bending moment comparison to predicate devices
- Screw Shear Off per ASTM F543
- Screw Pull Out per ASTM F543
- Screw Insertion per ASTM F543
- Cable Plug Static Traction
- Static Cantilever Bending
- Dynamic Cantilever Bending
- Multiple Usage Static Cantilever Bending

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 Testing:

Clinical testing was not required for this submission.

Conclusion:

The subject devices Pangea Utility Plating System and Pangea Platform are substantially equivalent to the previously cleared predicate devices PeriPRO Femur and Variable Angle Fixation (K222381). Except for the modifications described in this submission the subject devices are identical to the predicate devices, 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