August 18, 2023

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

Re: K231262
Trade/Device Name: Pangea Femur Plating System, Pangea Fibula Plating System, Pangea Tibia Plating System, Pangea Humerus 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: May 1, 2023
Received: May 1, 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)*
K231262

Device Name
Pangea Femur Plating System

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

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- 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)

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)*

K231262

Device Name
Pangea Fibula Plating System

Indications for Use *(Describe)*

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

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- 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)

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)*

K231262

Device Name
Pangea Tibia Plating System

Indications for Use *(Describe)*

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

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- 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)

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)*

K231262

Device Name

Pangea Humerus Plating System

Indications for Use *(Describe)*

Pangea Humerus Plating System:

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

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K231262
510(k) Summary

Proprietary Name:	Pangea™ Femur Plating System Pangea™ Fibula Plating System Pangea™ Tibia Plating System Pangea™ Humerus 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
Regulation Number:	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:	AxSOS 3 Ti System (K200398/K181091/ K153379/ K123964)
Additional Predicate:	SPS Small Fragment Set The Stryker® Plating System (K060798) VariAx Fibula (K081284) VariAx 2 One-Third Tubular Plating System (K151879) PeriPRO Femur and Variable Angle Fixation (K222381)
Description	This traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the Pangea Femur Plating System, Pangea Fibula Plating System, Pangea Tibia Plating System, and Pangea Humerus Plating System. This submission encompasses multiple systems that have similar intended use.

All plates are manufactured from Ti6Al4V ELI (ASTM F136), are anatomically pre-contoured. and are available in different sizes and left/right versions. The plates are provided sterile or non-sterile and range in length from 68 mm to 441 mm. The plates allow for the use of locking and non-locking screws and are used with cable plugs and washers.

Indications for Use

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

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

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

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

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

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

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

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

Summary of Technologies

A comparison of the systems demonstrated that the subject Pangea Femur Plating System, Pangea Fibula Plating System, Pangea Tibia Plating System, Pangea Humerus Plating System is substantially equivalent to the AxSOS 3 Ti (K181091/ K200398), SPS Small Fragment Set The Stryker® Plating System (K060798), VariAx 1/3 tubular (K151879), VariAx Fibula (K081284), and PeriPRO Femur and Variable Angle Fixation (K222381) in 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:

- Dynamic construct testing

Assessments performed to establish compatibility with a magnetic resonance environment:

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

Tests performed to establish compatibility with a magnetic resonance environment:

- RF Heating per ASTM F2182

Clinical Testing:

Clinical testing was not required for this submission.

Conclusion:

The subject device Pangea Femur Plating System, Pangea Fibula Plating System, Pangea Tibia Plating System, and Pangea Humerus Plating System are substantially equivalent to the previously cleared predicate device AxSOS 3 Ti (K200398/K181091/ K153379/ K123964). 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