October 6, 2024,

Stryker GmbH
Ashley Allison
Senior Regulatory Affairs Specialist
Bohnackerweg 1
Selzach, 2545
Switzerland

Re: K242445
Trade/Device Name: Pangea Platform; Pangea Femur Plating System; Pangea Humerus Plating System; Pangea Tibia 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: August 16, 2024
Received: August 16, 2024

Dear Ashley Allison:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242445

Device Name

Pangea Platform;
Pangea Femur Plating System;
Pangea Humerus Plating System ;
Pangea Tibia Plating System

Indications for Use *(Describe)*

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.

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 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

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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510(k) Summary

Proprietary name:	Pangea Platform, Pangea Femur Plating System, Pangea Humerus Plating System, and Pangea Tibia Plating System.
Common name:	Plate, Fixation, Bone and Screw, Fixation, Bone
Regulation Number:	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(s):	HRS, HWC
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Ashley Allison Senior Specialist, Regulatory Affairs 325 Corporate Dr Mahwah, NJ 07430 Phone: 269 845 7922 ashley.allison@stryker.com
Date Prepared:	August 16, 2024
Predicate Device:	Pangea Platform (K231257), Pangea Femur Plating System, Pangea Humerus Plating System, Pangea Tibia Plating System (K231262)
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 Pangea Platform, Pangea Femur Plating System, Pangea Humerus Plating System, and Pangea Tibia Plating System. This line extension consists of Class II instruments intended to assist in targeting.
Indications for Use:	**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. **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 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

Comparison to predicate device:

The indications of the subject devices are identical as those of the predicate devices. There is no change in the fundamental scientific technology shared by both the subject and predicate devices.

Performance Data:

Non-Clinical Performance:
The new subject devices of Pangea Platform, Pangea Femur Plating System, Pangea Humerus Plating System, and Pangea Tibia Plating System are reusable and provided non-sterile. Comparative assessment to the predicate and reference systems demonstrated substantial equivalence. Testing was performed on the subject devices to verify that the T20 and T15 targeting construct can withstand typical physical loads during its use using functional aging. A biocompatibility safety evaluation was performed per ISO 10993-1 to support the verification of biological safety.

Clinical Performance:
Clinical data was not needed for the subject devices to demonstrate substantial equivalence to the predicate devices.

Conclusion:

The subject devices have identical intended use and indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using same materials and processes as the predicate devices.
The performance analyses demonstrate that:

- Any differences do not raise new questions of safety and effectiveness; and
- The subject devices are at least as safe and effective as the legally marketed predicate devices.