February 3, 2026

Stryker GmbH
Ileana Freige
Staff Specialist Regulatory Affairs
Bohnackerweg 1
Selzach, Solothurn, Ch, 2545
Switzerland

Re: K253640
Trade/Device Name: T2 Alpha Femur Retrograde Nailing System; Pangea Femur Reconstruction System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HRS, HWC
Dated: January 29, 2026
Received: January 29, 2026

Dear Ileana Freige:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K253640 |

Please provide the device trade name(s).

T2 Alpha Femur Retrograde Nailing System;
Pangea Femur Reconstruction System

Please provide your Indications for Use below.

The T2 Alpha Femur Retrograde Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved. The indications for use of these internal fixation devices include:
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Supracondylar fractures, including those with intraarticular extension
- Fractures involving osteopenic and osteoporotic bone
- Fractures distal to a total hip prosthesis
- Periprosthetic fractures
- Nonunions and malunions

The Pangea Femur Reconstruction 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.
• Peri-implant fractures.
When used with the T2 Alpha Femur Retrograde Nailing System, the Pangea Femur Reconstruction System is used for the indications of the T2 Alpha Femur Retrograde Nailing System.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

# 510(k) Summary

| | |
|---|---|
| **Proprietary name:** | T2 Alpha Femur Retrograde Nailing System<br>Pangea Femur Reconstruction System |
| **Common name:** | Rod, Fixation, Intramedullary and accessories<br>Plate, fixation, bone |
| **Primary Product Code:** | HSB<br>HRS |
| **Regulation Number:** | 21 CFR 888.3020: Intramedullary fixation rod<br>21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories |
| **Associated Product Code(s):** | HWC |
| **Regulation Number:** | 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener |
| **Device Class:** | Class II |
| **Sponsor:** | Stryker GmbH<br>Bohnackerweg 1<br>2545 Selzach, Switzerland |
| **Contact Person:** | Ileana Freige<br>Staff Specialist, Regulatory Affairs<br>Dr. Homer Stryker Strasse 1<br>2545 Selzach, Switzerland<br>Phone: +41 79 757 61 27<br>ileana.freige@stryker.com |
| **Date Prepared:** | November 19, 2025 |
| **Predicate Device:** | T2 Alpha Femur Retrograde Nailing System (K250163)<br>Pangea Femur Plating System (K231262) |
| **Device Description:** | T2 Alpha Femur Retrograde Nailing System, previously cleared in K250163, consists of implants (intramedullary nails in various diameter and sizes, compression screw, end caps, distal lateral/medial struts and interlinking dowels), as well as non-sterile instrumentation.<br><br>The subject of this 510(k) submission is to introduce new devices of the T2 Alpha Femur Retrograde Nailing System. This line extension consists of shorter lengths of the pre-contoured lateral struts, and of a spanning attachment to be used together with the existing lateral struts. |

The struts and spanning attachments are manufactured from Ti6Al4V ELI (Type II anodization) and are available in left/right versions; these will be provided both non-sterile and sterile packaged.
Additionally, the purpose of this bundled submission is to rebrand some of the devices previously cleared in K250163 under the new Pangea Femur Reconstruction System. This system will consist of the distal lateral and medial femur plates, the dowels and the spanning attachments, as well as non-sterile instruments. The anatomically pre-contoured plates and interlinking dowels of this system will be used in combination with the existing nails of the T2 Alpha Femur Retrograde System for the treatment of complex fractures of the distal femur.

**Indications for Use:**

The T2 Alpha Femur Retrograde Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved. The indications for use of these internal fixation devices include:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Supracondylar fractures, including those with intraarticular extension
- Fractures involving osteopenic and osteoporotic bone
- Fractures distal to a total hip prosthesis
- Periprosthetic fractures
- Nonunions and malunions

The Pangea Femur Reconstruction 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.
- Peri-implant fractures.

When used with the T2 Alpha Femur Retrograde Nailing System, the Pangea Femur Reconstruction System is used for the indications of the T2 Alpha Femur Retrograde Nailing System.

**Comparison to predicate device:**

A comparison of the systems demonstrated that the subject T2 Alpha Femur Retrograde Nailing System and the Pangea Femur Reconstruction System are substantially equivalent to their corresponding predicate devices regarding intended use, indications, material, design and operational principles.

**Performance Data:**

*Non-Clinical Performance:*
Non-clinical testing and comparative assessments to predicate devices demonstrated substantial equivalence. The following factors were considered:

- Construct fatigue strength
- Cut-out performance
- Construct stiffness
- Bending strength
- Static cantilever bending
- Fretting corrosion per ASTM F897
- MR assessment of magnetically induced displacement force per ASTM F2052, magnetically induced torque per ASTM F2213, RF-induced heating per ASTM F2182, and image artifacts per ASTM F2119.
- Packaging tests were performed according to ISO 11607-1 and ISO 11607-2.
- Biocompatibility evaluation according to ISO 10993-1

**Conclusion:**

The subject T2 Alpha Femur Retrograde Nailing System is substantially equivalent to the previously cleared predicate device T2 Alpha Femur Retrograde Nailing System.

The subject Pangea Femur Reconstruction System is substantially equivalent to the previously cleared predicate device Pangea Femur Plating System and the T2 Alpha Femur Retrograde Nailing System.

The performance data and 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.