August 13, 2025

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

Re: K250163
Trade/Device Name: T2 Alpha Femur Retrograde Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC, HRS
Dated: August 11, 2025
Received: August 11, 2025

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 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2025.08.13 08:00:12 -04'00'

for: Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.

510(k) Number *(if known)*
K250163

Device Name
T2 Alpha Femur Retrograde Nailing System

Indications for Use *(Describe)*

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 struts of the T2 Alpha Femur Retrograde Nailing System are intended to be used only with the nails of this system; they are not to be used as stand-alone devices.

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.

510(k) Summary

Proprietary name:	T2 Alpha Femur Retrograde Nailing System
Common name:	Rod, Fixation, Intramedullary and accessories
Primary Product Code:	HSB
Regulation Number:	21 CFR 888.3020: Intramedullary fixation rod
Associated Product Code(s):	HWC, HRS
Regulation Number:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Ileana Freige Staff Specialist, Regulatory Affairs Dr. Homer Stryker Strasse 1 2545 Selzach, Switzerland Phone: +41 79 757 61 27 ileana.freige@stryker.com
Date Prepared:	January 21, 2025
Primary Predicate Device:	T2 Alpha Femur Retrograde Nailing System (K203819)
Predicate Devices:	Synthes Retrograde Femoral Nail Advanced System (K201346) GAP Endo-Exo Medullary System (K160545) Pangea Femur Plating System (K231262)
Device Description:	T2 Alpha Femur Retrograde Nailing System, previously cleared in K203819, consists of sterile implants (intramedullary nails in various diameter and sizes, compression screw and end caps), as well as non-sterile instruments (targeting devices). 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 anatomically pre-contoured struts and interlinking dowels designed to 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.

All struts are manufactured from Ti6Al4V ELI (Type II anodization) and are available in different sizes and left/right versions; these will be provided both non-sterile and sterile packaged. Interlinking dowels to the femoral nail are manufactured from CoCr and will be provided sterile packaged.

Indications for Use:

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 struts of the T2 Alpha Femur Retrograde Nailing System are intended to be used only with the nails of this system; they are not to be used as stand-alone devices.

Comparison to predicate device:

The intended use and indications of the subject devices are identical as those of the predicate device. There is no change in the fundamental scientific technology shared by both the subject and predicate devices. Except for the dowels which are made of CoCr, both the subject and predicate devices are manufactured from the same material (Ti6Al4V).

The technological characteristics of the T2 Alpha Retrograde Nailing System are the same or similar to the ones of the predicate devices. The subject devices utilize the same nail and screws as the primary predicate device for fracture fixation of the femur. The subject devices are intended for use as a linked construct with an IM nail, same as the predicate devices.

Performance bench testing and engineering assessments demonstrate that the performance of the subject devices is equivalent to the performance of the predicate devices.

Performance Data:

Non-Clinical Performance:

The T2 Alpha Femur Retrograde implants are single use devices, available in sterile and non-sterile presentations. Sterile devices are sterilized by means of radiation.

Non-clinical testing and comparative assessment to the predicate devices demonstrated substantial equivalence. The following factors were considered:

- Construct fatigue strength
- Cut-out performance
- Construct stiffness
- Shear-Off, Pull-Out and Insertion
- Static cantilever bending
- Fretting corrosion per ASTM F897
- Targeting Accuracy
- 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

Clinical Performance:

Clinical evidence from peer-reviewed scientific literature is included in support of this submission.

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 labeling and are manufactured and sterilized using the same materials and processes as the predicate devices.

The performance analyses demonstrate that:

- Any differences do not raise different questions of safety and effectiveness; and
- The subject devices are substantially equivalent to the predicate devices.