August 20, 2025

Stryker GmbH
Jackie Perri
Staff Specialist, Regulatory Affairs
Bohnackerweg 1
Selzach, 2545
Switzerland

Re: K251400
Trade/Device Name: T2 Alpha Humerus Nailing System; IMN Screws System; T2 Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: May 6, 2025
Received: July 21, 2025

Dear Jackie Perri:

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: 2025.08.20 13:17:25 -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.

Submission Number *(if known)*

K251400

Device Name

T2 Alpha Humerus Nailing System;
IMN Screws System;
T2 Nailing System

Indications for Use *(Describe)*

The T2 Alpha Humerus Nailing System is indicated for the treatment of humerus fractures. Fractures can include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures.

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

The T2 Humeral Nail is intended to provide temporary stabilization of various types of fractures, malunions, and non-unions of the humerus. The nails are inserted using an open or closed technique and can be static, dynamic, or compression locked. The subject and predicate devices are indicated for use in the humerus. Types of fractures include, but are not limited to, fractures of the humeral shaft, non-unions, malalignments, pathological humeral fractures, and impending pathological 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.

510(k) Summary

Proprietary name:	T2 Alpha Humerus Nailing System IMN Screws System T2 Nailing System
Common name:	Rod, fixation, intramedullary, and accessories Screw, fixation, bone.
Regulation Number:	21 CFR 888.3020: Intramedullary fixation rod 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Product Code(s):	HSB HWC
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Jackie Perri Staff Specialist, Regulatory Affairs Stryker 325 Corporate Drive Mahwah, NJ 07430 jackie.perri@stryker.com
Date Prepared:	May 06, 2025
Predicate Device:	Primary Predicate: T2 Nailing System (K032523) Additional Predicate: Tornier Humeral Nail and Tornier Long Humeral Nail (K230352) IMN Screws System (K213328)
Device Description:	The T2 Alpha Humerus Nailing System is an intramedullary humerus fracture nailing system consisting of sterile implants (Nails, End Caps, Compression Screw, and Washer) and non-sterile indication-specific instrumentation. The Nails, End Caps, Compression Screw, and Washer are made of titanium alloy as per ASTM F136. The T2 Alpha Humerus Nailing System will be used with the existing Locking Screws and Advanced Locking Screws of the IMN Screws System. The IMN Screws System includes bone screws (Locking Screws and Advanced Locking Screws) that are inserted through the

intramedullary nail to stabilize the nail-bone construct. All screws are sterile and made of titanium alloy (Ti6Al4V ELI) per ASTM F136.

The T2 Humeral Nail System is an intramedullary nailing system that allows antegrade and retrograde humeral nailing. The nails, end caps, compression screw, and washer are provided sterile and made of titanium alloy as per ASTM F136.

Indications for Use:

The T2 Alpha Humerus Nailing System is indicated for the treatment of humerus fractures. Fractures can include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures.

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

The T2 Humeral Nail is intended to provide temporary stabilization of various types of fractures, malunions, and non-unions of the humerus. The nails are inserted using an open or closed technique and can be static, dynamic, or compression locked. The subject and predicate devices are indicated for use in the humerus. Types of fractures include, but are not limited to, fractures of the humeral shaft, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

Comparison to predicate device:

The intended use and indications of the T2 Alpha Humerus devices are comparable to those of the predicate devices. The subject device is introducing new nail diameters (10, 11, and 12 mm). The subject device implants and the predicate device implants are both sterile and manufactured from titanium alloy. There is no change in the fundamental scientific technology shared by both the subject and predicate devices.

The intended use and indications of the IMN Screw devices are identical to those of the predicate device. The advanced locking screw lengths of the subject device are shorter in length (Ø4mm – 20, 22.5, and 25 mm). The subject device implants and the predicate device implants are both sterile and manufactured from titanium alloy. There is no change in the fundamental scientific technology shared by both the subject and predicate devices.

The intended use and indications of the T2 devices are identical to those of the predicate device. The new sterile washers are similar to the current washer previously cleared in this system, made of titanium alloy as per ASTM F136. The subject device implants and the predicate device implants are both sterile and manufactured from titanium alloy. There is no change in the fundamental scientific technology shared by both the subject and predicate devices.

Performance Data:	Non-Clinical Performance: The T2 Alpha Humerus Nailing system implants are single-use, sterile devices. These implants are sterilized using gamma irradiation. The T2 Alpha Humerus Nailing system also comprises instruments that are provided non-sterile. The IMN Screws are single-use sterile devices. These screws are sterilized using gamma irradiation. Comparative assessment of the predicate and reference systems demonstrated substantial equivalence. The following factors were considered: Dynamic 4 Point Bending Static 4 Point Bending Static Torsional Stiffness Targeting Accuracy Insertion Torque and Pull-out Force 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 data were not needed for the subject devices to demonstrate substantial equivalence to the predicate devices.
Conclusion:	The subject devices have similar intended use and indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design and labeling, and are manufactured and sterilized using the same materials and processes as the predicate device. The performance analyses demonstrate that: Any differences do not raise different questions of safety and effectiveness; and The subject devices are at least as safe and effective as the legally marketed predicate device.