Stryker GmbH
Cindy Leon
Staff Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

February 11, 2022

Re: K213328
Trade/Device Name: Gamma4 System, Gamma3 System, IMN Screws System, T2 Tibial Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: January 10, 2022
Received: January 11, 2022

Dear Cindy Leon:

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,

For Jiping Chen, M.D., Ph.D., M.P.H.
Acting Division 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213328

Device Name
Gamma4 System

Indications for Use *(Describe)*

The Gamma4 System is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur (including osteoporotic and osteopenic bone).

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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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)*

K213328

Device Name
Gamma3 System

Indications for Use *(Describe)*

The Gamma3 System is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur (including osteoporotic and osteopenic bone).

The U-Blade Lag Screw is also indicated for rotationally unstable 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213328

Device Name
IMN Screws System

Indications for Use *(Describe)*
The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

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)

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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)*

K213328

Device Name
T2 Tibial Nailing System

Indications for Use *(Describe)*

The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

The Locking Screws may also be used in conjunction with the T2 Alpha Systems.

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)

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Section 9: 510(k) Summary

I. SUBMITTER

Sponsor: Stryker GmbH
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Date Prepared: October 4, 2021

II. DEVICE

Name of Device: Gamma4 System
Gamma3 System
IMN Screws System
T2 Tibial Nailing System

Common Name: Gamma4 System
Rod, fixation, intramedullary and accessories
Gamma3 System
Rod, fixation, intramedullary and accessories
IMN Screws System
Screw, fixation, bone
T2 Tibial Nailing System
Rod, fixation, intramedullary and accessories

Regulation Number / Name: Gamma4 System
21CFR 888.3020 (Intramedullary fixation rod)

	Gamma3 System 21CFR 888.3020 (Intramedullary fixation rod) IMN Screws System 21CFR 888.3040 (Smooth or threaded metallic bone fixation fastener) T2 Tibial Nailing System 21CFR 888.3020 (Intramedullary fixation rod)
Product Code:	Gamma4 System HSB (Rod, fixation, intramedullary and accessories) Gamma3 System HSB (Rod, fixation, intramedullary and accessories) IMN Screws System HWC (Screw, fixation, bone) T2 Tibial Nailing System HSB (Rod, fixation, intramedullary and accessories)
Regulatory Class:	Class II

III. PREDICATE DEVICE

Primary Predicate:	Gamma3 System (K200869)
Additional Predicates:	T2 Alpha Femur Antegrade GT/PF Nailing System (K203819) Zimmer Natural Nail System Cephalomedullary Nails (K192312) IMN Screws System (K193308) T2 Tibial Nailing System (K203819)

IV. DEVICE DESCRIPTION

This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the Gamma4 System and align labeling across the Gamma3 System, IMN Screws System and T2 Tibial Nailing System.

This submission encompasses multiple systems (Gamma4 System, Gamma3 System, IMN Screws and T2 Tibial Nailing System) that have similar intended use and/or will be used together during the surgical procedure.

The Gamma4 System is a hip fracture nailing system and includes sterile implants (Trochanteric and Long Nails in various diameters and sizes, Lag Screws, and End Caps) as well as non-sterile instruments (targeting devices). The nails, lag screws and end caps are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136. The targeting device is manufactured from stainless steel per AISI 431, carbon fiber reinforced PEEK and PEEK unreinforced.

The Gamma4 System will be used with the existing Locking Screws and Advanced Locking Screws of IMN Screws System (K193308), the Distal Targeting Device Femur Antegrade and Adjusting Device Femur Antegrade of IMN Instruments System (K191271), the ADAPT Clip of the Gamma3 System (K200869) as well as the surgical instruments of T2 Tibia Nailing System (510(k) exempt devices).

<u>Gamma3 System</u>
The Gamma3 System most recently cleared in K200869 is a hip fracture nailing system and includes sterile implants (Trochanteric Nails, Long Nails, standard Lag Screws, U-Blade Lag Screw set, distal locking screws, a set screw and end caps in various diameter and sizes) as well as non-sterile instruments (targeting devices).

The sterile implants (nails, set screw and end cap) are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and stainless-steel alloy per ASTM F1586. The targeting devices are manufactured from stainless steel and carbon fiber reinforced PEEK.

The Gamma3 System is used with the IMN Ø5 mm locking screws most recently cleared in K193308 as well as other instruments associated with implantation of the Gamma3 System and standard Class I exempt surgical instruments.

IMN Screws System

The IMN Screws System, most recently cleared in K193308, includes bone screws (Locking Screws and Advanced Locking Screws) that are inserted through the intramedullary nail to stabilize the nail-bone construct. The Ø5 mm Locking Screws and Advanced Locking Screws are inserted through the distal locking holes of the Gamma4 nails. All screws are made of titanium alloy (Ti6Al4V ELI) per ASTM F136. Refer to Attachment 15-5 for the list of devices that are compatible with the IMN Screws System.

T2 Tibial Nailing System

The T2 Tibial Locking Nail, most recently cleared in K203819, is a cylindrical tube manufactured from titanium alloy and slightly bowed to accommodate the shape of the tibia. Locking screws, compression screws and various end caps are manufactured from titanium alloy and are used with the nails. The T2 Tibial Locking Nail is available in two versions, each differing from the other only in diameter, length and number and orientation of screw holes.

V. INTENDED USE

Gamma4 System

The Gamma4 System is intended to achieve functionally stable osteosyntheses and stabilization of bones and bone fragments.

Gamma3 System

The Gamma3 System is intended to achieve functionally stable osteosyntheses and stabilization of bones and bone fragments.

IMN Screws System

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

T2 Tibial Nailing System

The T2 Tibial Locking Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

VI. INDICATION FOR USE

Gamma4 System

The Gamma4 System is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur (including osteoporotic and osteopenic bone).

Gamma3 System

The Gamma3 System is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur (including osteoporotic and osteopenic bone).

The U-Blade Lag Screw is also indicated for rotationally unstable fractures.

IMN Screws System

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

T2 Tibial Nailing System

The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

The Locking Screws may also be used in conjunction with the T2 Alpha Systems.

Summary of Technologies

A comparison of the system demonstrated that the subject Gamma4 System is substantially equivalent to the following predicates in regards to intended use, material, design, and operational principles:

- Gamma3 System (K200869)
- T2 Alpha Femur Antegrade GT/PF Nailing System (K203819)
- Zimmer Natural Nail System Cephalomedullary Nail (K192322)

There are no changes in technology for the Gamma3 System, IMN Screws System and T2 Tibial Nailing System, as there was only a labeling change made in this submission.

Non-Clinical Testing

The following non-clinical laboratory testing, and performance assessments were made in support of substantial equivalence

The following tests were performed:

- Construct Fatigue Strength Testing
- Cut-out testing
- Targeting accuracy testing
- Induced Displacement
- Induced Torque
- RF Heating
- Image Artifacts

The following performance assessment was conducted:

- Testing of mechanical properties per ASTM F1264

CLINICAL TESTING

Clinical testing was not required for this submission.

CONCLUSION

Gamma4 System

The subject Gamma4 System is substantially equivalent to the previously cleared Gamma3 System (K200869) primary predicate system, the T2 Alpha Femur Antegrade GT/PF Nailing System (K203819) and the Zimmer Natural Nail System Cephalomedullary (K192312) additional predicates.

Gamma3 System

The subject Gamma3 System is substantially equivalent to the previously cleared Gamma3 System (K200869) primary predicate system and the Zimmer Natural Nail System Cephalomedullary (K192312) additional predicate.

IMN Screws System

The subject IMN Screws System is substantially equivalent to the previously cleared IMN Screws System (K193308) primary predicate system and the Zimmer Natural Nail System Cephalomedullary (K192312) additional predicate.

T2 Tibial Nailing System

The subject T2 Tibial Nailing System is substantially equivalent to the previously cleared T2 Tibial Nailing System (K203819) primary predicate system and the Zimmer Natural Nail System Cephalomedullary (K192312) additional predicate.