July 22, 2020

Stryker Trauma GmbH
Sanja Jahr
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K200869
Trade/Device Name: Gamma3 System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 22, 2020
Received: June 23, 2020

Dear Sanja Jahr:

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 Michael Owens, MS, RAC
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200869

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Proprietary Name:	Gamma3 System
Common Name:	Rod, Fixation, Intramedullary And Accessories
Regulation Description:	Intramedullary fixation rod
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Device Class:	II
Sponsor:	Stryker Trauma GmbH Prof.-Kuentscher-Str. 1-5 24232 Schoenkirchen / Germany
Contact Person:	Ms. Sanja Jahr Staff Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: 201.831.6797 Fax: 201-831-6020
Date Prepared:	March 31, 2020
Primary Predicate:	Gamma3 and T2 Recon Targeting Devices (K123401)
Additional Predicates:	T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System, IMN Screws System, IMN Instruments System (K191271) Zimmer Natural Nail System (K172114) Trigen InterTAN (K040212) Howmedica Gamma3 Nail System (K043431 and K034002)

Description

The Gamma3 System consists of Trochanteric Nails, Long Nails, standard Lag Screws, U-Blade Lag Screws, end caps, set screws, distal locking screws, and instrumentation. The purpose of this traditional 510(k) is to update and consolidate system indications and intended use, update MR labeling to reflect new testing, update the mechanical testing analysis, and reference Ø5mm IMN Screws System Locking Screws as compatible components. Additional labeling changes were also made, including operative technique consolidation, safety information updates, and the addition of the MR Conditional symbol to package labels.

Gamma3 Trochanteric Nail:
The Gamma3 Trochanteric Nail is available in distal diameters ranging from 10 to 12mm and lengths of 170mm, 180mm, and 200mm. 170mm and 180mm nails have a single, oblong hole distally, while the 200mm nail has both an oblong hole and a round hole for distal fixation. The oblong hole allows for both static and dynamic locking configurations. All Trochanteric Nails are locked proximally with a Lag Screw or U-Blade Lag Screw. The set screw engages with the lag screw and allows translation while preventing rotation. End caps close off the top of the nail and are available in 0mm, +5mm, and +10m lengths.

Nails, set screws, and end caps are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and stainless steel alloy per ASTM F1586. Stainless steel nails are offered in 11mm and 12mm diameters only. Titanium alloy implants have a type II anodized surface treatment.

Gamma3 Long Nail*:*
The Gamma3 Long Nail is available in lengths ranging from 240mm to 480mm in both R1.5m and R2.0m antecurvatures. The proximal nail diameter is 15.5mm. Distal nail diameters include 10mm, 11mm, 13mm, and 15mm for R1.5m and 11mm, 13mm, and 15mm for R2.0. Distally, there is one round hole and one oblong hole, allowing both static and dynamic locking configurations. All Long Nails are locked proximally with a Lag Screw or U-Blade Lag Screw. Set screws and end caps are identical to what's described for the Trochanteric nail. The Long Nail is available in titanium alloy (Ti-6Al-4V) per ASTM F136 and stainless steel alloy per ASTM F1586. The stainless steel long nail is only available in R2.0 and 11mm.

Lag Screw
Lag screws are cannulated with a major diameter of 10.5mm and lengths ranging from 70mm to 130mm. They are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and stainless steel alloy per ASTM F1586.

U-Blade Lag Screw
The U-Blade Lag Screw is used in combination with a U-Blade. The U-Blade Lag Screw has a major diameter of 10.5mm. The U-Blade slides over the U-Blade Lag Screw, resulting in the spreading of the U-Blade at the tip of the screw to 12.5mm. The construct is fixated by the dedicated end cap. The U-Blade Lag Screw and U-Blade are offered in the same lengths as the standard lag screws. They are available in Ti-6Al-4V.

Distal Locking Screws
Distal locking screws are cannulated and fully threaded, with a diameter of 5.0mm and lengths ranging from 25mm to 120mm. They are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and stainless steel alloy per ASTM F1586.

Gamma3 Instrumentation:
Gamma3 instrumentation consists of class II (implant-specific) targeting devices which help facilitate insertion of the nails, lag screws, and distal locking screws. Targeting devices are manufactured from stainless steel per AISI 431 and carbon fiber reinforced PEEK. They were cleared under K123401. Other instrumentation includes drills, drill guides, k-wires, and screw drivers.

Indications for Use

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.

Summary of Technologies

A comparison of the systems demonstrated that the subject Gamma3 System is substantially equivalent to the following predicates in regards to intended use, material, design, and operational principles:

- Gamma3 and T2 Recon Targeting Devices (K123401)
- T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System, IMN Screws System, IMN Instruments System (K191271)
- Zimmer Natural Nail System (K172114)
- Trigen InterTAN (K040212)
- Howmedica Gamma3 Nail System (K043431 and K034002)

Non-Clinical Testing

The following non-clinical laboratory testing was performed to establishing equivalence to predicates, including:

- Construct Fatigue Testing
- Lag Screw Cut-Out testing
- MR Compatibility per FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" (December 11, 2014) and the following standards:
    - Magnetically Induced Displacement Force per ASTM F2052
    - Magnetically Induced Torque per ASTM F2213
    - Heating by RF Fields per ASTM F2182
    - Image Artifacts per ASTM F2119

Testing demonstrated that Gamma3 System is substantially equivalent in mechanical performance to the predicate device, Zimmer Natural Nail System (K172114).

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject Gamma3 System is substantially equivalent to the predicates listed above.