June 9, 2023

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

Re: K230512
Trade/Device Name: Gamma4 System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 25, 2023
Received: May 25, 2023

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.06.09 16:04:36 -04'00'

Farzana Sharmin, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230512

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). The RC 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 9: 510(k) Summary

I. SUBMITTER

Sponsor: Stryker GmbH
Bohnackerweg 1
2545 Selzach / Switzerland

Contact Person: Cindy Leon
Sr. Staff Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, NJ 07430
Phone: 201-831-5374
Fax: 201-831-6020

Date Prepared: February 24, 2023

II. DEVICE

Name of Device: Gamma4 System

Common Name: Gamma4 System
Rod, fixation, intramedullary and accessories

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

Product Code: Gamma4 System
HSB (Rod, fixation, intramedullary and accessories)

Regulatory Class: Class II

III. PREDICATE DEVICE

Primary Predicate: Gamma3 System (K213328)

Additional Predicates: T2 Alpha Femur Antegrade GT/PF Nailing System (K203819)

IV. DEVICE DESCRIPTION

This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market new devices into the Gamma4 System, add new indications for use for the RC Lag Screws and update the current surgical technique to include an optional section to use bone void fillers.

The Gamma4 System was previously cleared in K222309, 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 subject devices (Intermediate Nails and RC Lag Screw) are also sterile implants in various diameters and sizes as well as a non-sterile Intermediate Targeting Sleeve. All nails and screws are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136 and the targeting device is manufactured from stainless steel per AISI 431, carbon fiber reinforced PEEK and PEEK unreinforced.

V. INTENDED USE

Gamma4 System

The introduction of the Intermediate Nails, RC Lag Screw and Intermediate Targeting Sleeve does not alter the intended use of the subject system previously cleared in K222309. The intended use is provided below:

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

VI. INDICATIONS 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).

The RC Lag Screw is also indicated for rotationally unstable fractures.

Summary of Technologies

A comparison of the systems 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 (K213328)
- T2 Alpha Femur Antegrade GT/PF Nailing System (K203819)

Non-Clinical Testing

The following performance assessment was made in support of substantial equivalence:

The following tests were performed:

- Targeting accuracy testing
- Bending Fatigue Strength per ASTM F1264

The following performance assessment was conducted:

- Construct Fatigue Strength Testing
- Cut-out testing
- Torsional Stiffness per ASTM F1264
- MR evaluation

Testing demonstrated that the Gamma4 System is equivalent in mechanical performance to the Gamma3 System primary predicate device (K213328) and T2 Alpha Femur Antegrade GT/PF Nailing System (K203819) additional predicate device.

CLINICAL TESTING

Clinical testing was not required for this submission.

CONCLUSION

The subject Gamma4 System is substantially equivalent to the previously cleared Gamma3 System (K213328) primary predicate.