Stryker GMBH
Tina Mornak
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

October 12, 2018

Re: K181848
Trade/Device Name: ADAPT for Gamma3, Gamma3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HSB
Dated: September 14, 2018
Received: September 17, 2018

Dear Tina Mornak:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S
2018.10.12 13:46:46 -04'00'

For:
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181848

Device Name
ADAPT for Gamma3

Indications for Use *(Describe)*

The ADAPT for Gamma3 System, when used with the Stryker Navigation System, assists the surgeon to determine the needed size and position of orthopedic implants during femur fracture surgery using the Gamma3 System.

When used in operation the system should be operated only by trained personnel such as surgeons and clinic staff.

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:

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181848

Device Name
Gamma3

Indications for Use *(Describe)*

The Trochanteric Gamma3 Nail is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections, while the Long Length Gamma3 Nail indication may include fractures resulting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

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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510(k) Summary

Proprietary Name:	ADAPT for Gamma3 Gamma3
Common Name:	Orthopedic Stereotaxic Instrument Rod, fixation, intramedullary and accessories
Regulation Description:	Stereotaxic instrument Intramedullary Fixation Rod
Regulation Number:	21 CFR 882.4560: Stereotaxic instrument 21 CFR 888.3020: Intramedullary Fixation Rod
Product Code:	OLO, HSB
Device Class:	II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Tina Mornak Senior Regulatory Affairs Specialist t: 201-831-6365 f: 201-831-6500 tina.mornak@stryker.com
Date Prepared:	July 6, 2018
Primary Predicate:	ADAPT for Gamma3 System: K173946
Additional Predicate:	Gamma3 System: K123401 Stryker PROFESS System: K141551

Description

The purpose of this submission is to introduce a new platform, ADAPT mobile, to the existing Stryker Navigation System. The ADAPT mobile platform will be used to run the previously cleared ADAPT 2.0 for Gamma3 SW (K173946) for use with the Gamma3 System (K123401).

The ADAPT for Gamma3 System consists of a software (ADAPT 2.0 for Gamma3 SW) and is compatible with hardware platforms, reference devices as well as Gamma3® implants and instruments. The software is designed to operate on the Stryker Navigation platforms (hardware platforms) and assists the surgeon to intraoperatively determine the size and position of Gamma3 implants during femur fracture surgery.

The Gamma3 Nail System is a family of intramedullary nails for basilar neck, intertrochanteric neck, peritrochanteric, subtrochanteric and femoral shaft fractures. The system consists of nails, lag screws, locking screws and screw sets.

Intended Use

ADAPT for Gamma3
The ADAPT for Gamma3 System, when used with the Stryker Navigation System, is a computer controlled stereotaxic image guided surgery system intended to provide static location information derived from image processing of intraoperatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images.

Gamma3
The intended use of the Gamma3 Nail System includes the following:

Trochanteric Gamma3 Nail
The Trochanteric Gamma3 Nail is intended for use in stabilizing various types of stable and unstable intertrochanteric fractures including peritrochanteric fractures.

Long Length Gamma3 Nail
The Long Length Gamma3 Nail is intended for fixation of stable and unstable femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10cm proximal to the intercondylar notch including fractures of the basilar neck, intertrochanteric neck, peritrochanteric fractures, subtrochanteric fractures and femoral shaft fractures.

Indications for Use

ADAPT for Gamma3
The ADAPT for Gamma3 System, when used with the Stryker Navigation System, assists the surgeon to determine the needed size and position of orthopedic implants during femur fracture surgery using the Gamma3 System.

When used in operation, the system should be operated only by trained personnel such as surgeons and clinic staff.

Gamma3
The Trochanteric Gamma3 Nail is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections, while the Long Length Gamma3 Nail indication may include fractures resulting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

Summary of Technologies

A comparison of the systems demonstrated that the subject ADAPT for Gamma3 System and Gamma3 System are substantially equivalent to the predicate ADAPT for Gamma3 System (K173946) and Gamma3 System (K123401) regarding intended use, material, design, and operational principles.

Non-Clinical Testing

Non-clinical testing was performed, including:

- Electrical safety and system safety per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-1-2
- Formative and summative usability evaluation per IEC 62366-1 and IEC 60601-1-6

- Reliability over lifetime for the ADAPT mobile PC Unit and the ADAPT mobile Operating System

Testing demonstrated that ADAPT mobile is equivalent in performance to the predicate ADAPT for Gamma3 System (K173946).

Clinical Testing

Clinical data is not required in support of this submission.

Conclusion

The subject ADAPT for Gamma3 System and Gamma3 System are substantially equivalent to the predicate ADAPT for Gamma3 System (K173946) and Gamma3 System (K123401).