Stryker GmbH
Nesli Karakaya
Regulatory Affairs
Associate Manager, Trauma & Extremities
Bohnackerweg 1
Selzach, 2545
Switzerland

May 2, 2018

Re: K173946
Trade/Device Name: ADAPT for Gamma3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 21, 2018
Received: March 29, 2018

Dear Nesli Karakaya:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8: Indications for Use Statement (FDA FORM 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ADAPT for Gamma 3

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.

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I. SUBMITTER

Sponsor: Stryker GmbH
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Date Prepared: December 19, 2017

II. DEVICE

Name of Device: ADAPT for Gamma3

Common Name: ADAPT for Gamma3
Orthopedic stereotaxic instrument

Regulation Number / Name: ADAPT for Gamma3
21CFR 882.4560 (Stereotaxic Instrument)

Product Code: ADAPT for Gamma3
OLO (Orthopedic Stereotaxic Instrument)

Regulatory Class: Class II

III. PREDICATE DEVICE

ADAPT for Gamma3

Primary predicate: FluoroMap Computer Assisted Surgery System (K103400)

IV. DEVICE DESCRIPTION

This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the ADAPT for Gamma3 System.

ADAPT for Gamma3

In the scope of this 510(k), two medical devices are introduced:

- ADAPT 2.0 for Gamma3 SW – Software (stored on a USB stick as a data carrier) for Gamma3® surgery assistance
- ADAPT Gamma3 DTS Clip – Reference body enabling distal locking assistance with ADAPT 2.0 for Gamma3 SW

ADAPT 2.0 for Gamma3 SW is a software which is designed to be run on the existing Stryker ADAPT® Platform (K141551) and Stryker NAV3 Platform (K162937). The software is based on the existing FluoroMap® 1.0 software which belongs to the predicate device FluoroMap Computer Assisted Surgery System (K103400).

ADAPT 2.0 for Gamma3 SW (when using with specific reference bodies: FluoroDiscs [K103400], ADAPT Clip [K103400], ADAPT Gamma3 DTS Clip [in the scope of this submission]) assists the surgeon with implant alignment, lag screw length determination, lag screw positioning and distal locking during Gamma3® surgery.

ADAPT 2.0 for Gamma3 SW uses fluoroscopic X-ray images taken during the surgical procedure. The software uses the reference bodies to perform registration of the surgical site and to assist the surgeon in the selection and placement of orthopedic implants. The registration is based on the geometry of embedded metal marker beads in the reference bodies. The software detects radiopaque implants and instruments such as nails, K-wires, lag screws and drill sleeves and displays positional information to the surgeon to provide assistance in positioning of implants during Gamma3® surgery.

The ADAPT Gamma3 DTS Clip is used as a reference body enabling distal locking assistance (for Gamma3® Long Nails) with ADAPT 2.0 for Gamma3 SW. The ADAPT Gamma3 DTS Clip consists of a PEEK body and contains radiopaque metal marker beads (DIN 5401 - 2 G20 – 1.3541). For assembly on the Gamma3® Distal Targeting Adjusting Device (part of Gamma3® Distal Targeting System), a specific assembly mechanism is integrated. The software (ADAPT 2.0 for Gamma3 SW) detects the metal marker beads of the assembled ADAPT Gamma3 DTS Clip on X-ray images to enable assistance.

V. 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 intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images

VI. INDICATION 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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ADAPT for Gamma3

Device comparison demonstrated that the ADAPT for Gamma3 is substantially equivalent to the previously cleared FluoroMap Computer Assisted Surgery System (K103400), in regards to intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

ADAPT 2.0 for Gamma3 SW

The following non-clinical testing was performed for the ADAPT for Gamma3 System:

- Different simulated use case scenarios – to verify a system accuracy of 2 mm. These scenarios include saw bone tests and simulated use tests.
- Functional system tests – to validate the product against all system requirements.
- Component and integration tests – to validate the product against the component requirements.
- Code reviews – to ensure the quality of the software coding.
- Safety tests (part of system tests) – to verify that all risk measures were implemented.
- Formative and summative usability studies

Testing demonstrated that ADAPT for Gamma3 is equivalent in performance to the predicate device (K103400).

ADAPT Gamma3 DTS Clip

For the ADAPT Gamma3 DTS Clip, that has direct patient contact (limited: ≤24 hours), the following tests were performed.

- Biocompatibility testing was performed to evaluate the biological safety of the ADAPT Gamma3 DTS Clip according to FDA Guidance 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'. Testing demonstrated that the ADAPT for Gamma3 DTS Clip is biocompatible.
- In addition, instrument corrosion, cleaning/disinfection, sterilization, reprocessing aging, functional aging, drop test, functional test, transport simulation as well as interaction of ADAPT 2.0 for Gamma3 SW and ADAPT Gamma3 DTS Clip were evaluated.

IX. CLINICAL TESTING

ADAPT for Gamma3

No clinical testing of the ADAPT for Gamma3 System has been conducted.

X. CONCLUSION

ADAPT for Gamma3

ADAPT for Gamma3 is substantially equivalent to the predicate device (K103400), identified in this premarket notification.