December 18, 2020

Stryker GmbH
Ugochi Okereke
Senior Regulatory Affairs Specialist
Contact Address325 Corporate Drive
Mahwah, New Jersey 07430

Re: K202749
Trade/Device Name: ADAPT for Gamma3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 18, 2020
Received: September 21, 2020

Dear Ugochi Okereke:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K202749

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.

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510(k) Summary

Proprietary Name:	ADAPT for Gamma3
Common Name:	Orthopedic Stereotaxic Instrument
Regulation Description:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560: Stereotaxic Instrument
Product Code:	OLO
Device Class:	II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Ugochi Okereke Senior Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5083 Fax: (201) 831-6500
Date Prepared:	December 18, 2020
Primary Predicate:	ADAPT for Gamma3: K181848

Description

The purpose of this 510(k) is to introduce the ADAPT 2.1 for Gamma3, an update to the existing software cleared in K181848. The ADAPT for Gamma3 Software is a surgical navigation system intended to be used with the Gamma3 Nail system, cleared in K200869. The updated software, in conjunction with the ADAPT mobile- Digital Port Connector, allows the ADAPT mobile PC unit to receive and process images from c-arms with flat panel detectors and/or digital signals. The ADAPT 2.1 for Gamma3 software supports all features which were already supported by the existing ADAPT 2.0 for Gamma3 software cleared in K181848.

Indications for Use

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.

Summary of Technologies

A comparison of the systems demonstrated that the subject ADAPT for Gamma3 System is substantially equivalent to the predicate ADAPT for Gamma3 system (K181848) in regard to intended use, material, design, and operational principles.

The intended use, design, and fundamental scientific technology are identical between the subject and predicate device. The changes do not constitute a new intended use, and do not affect the control mechanism, operating principle, or energy type. All other predicate and subject device attributes are either identical, except for the software changes subject to this notification. The software changes are being implemented to additionally provide flatpanel C-arm compatibility. Therefore resulting in a difference in the procedural workflow.

Verification and validation testing has been completed on the subject device and the results confirm that no new or different questions of safety and effectiveness have been raised that pose a significant risk to the safety or effectiveness of the subject device. The information provided within this notification demonstrates that the subject device is at least as safe and effective as their predicate and supports a determination of substantial equivalence.

Based on the above and the information in the comparison table within this notification, Stryker GmbH believes that sufficient evidence exists to reasonably conclude that the proposed ADAPT for Gamma3 System is substantially equivalent.

Non-Clinical Testing

Non-clinical testing was performed, including:

- 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.

Testing demonstrated that the subject ADAPT for Gamma3 system is equivalent in performance to the predicate ADAPT for Gamma3 system, cleared in K181848.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject ADAPT for Gamma3 is substantially equivalent to the predicate ADAPT for Gamma3 system.