June 10, 2022

Stryker GmbH
Danielle Madureira
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K210582
Trade/Device Name: EasyClip® and EasyClip® Xpress
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: June 3, 2022
Received: June 6, 2022

Dear Danielle Madureira:

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,

Limin Sun, 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)*

K210582

Device Name
EasyClip®

Indications for Use *(Describe)*
The EasyClip® staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis in adults and pediatrics (children and adolescents).

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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"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."

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)*

K210582

Device Name
EasyClip® Xpress

Indications for Use *(Describe)*
The EasyClip® Xpress Staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis in adults and pediatrics (children and adolescents).

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:	EasyClip® & EasyClip® Xpress
Common Name:	Staple, Fixation, Bone
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories.
Regulation Number:	21 CFR 888.3030
Classification Product Code:	JDR
Device Class:	II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Danielle Jannuzzi Madureira, PhD Associate Manager, Regulatory Affairs Dr. Homer Stryker Strasse, 1 CH-2545 Selzach, Switzerland Phone: +41 79 890 02 89 Fax: +41 32 641 66 60
Date:	June 10, 2022
Primary Predicate Device:	EasyClip® (Memory Metal Staples) - K122113
Additional Predicate Device:	EasyClip® Xpress - K162321
Device Description:	The EasyClip® & EasyClip® Xpress, previously cleared in K122113 and K162321, includes superelastic bone staples shape memory Nitinol per ASTM F2063-18. The subject of the bundled submission introduces a contraindication for both systems and packaging change for EasyClip.
Indications for Use:	The EasyClip® staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis in adults and pediatrics (children and adolescents). The EasyClip® Xpress Staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis in adults and pediatrics (children and adolescents).
Comparison to Predicate Device:	The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. The introduction of a contraindication (EasyClip® and EasyClip® Xpress) and the packaging change (EasyClip) does not alter the fundamental scientific technology shared by both the subject devices and predicate devices.
Performance Data (Nonclinical):	*Non-Clinical Performance and Conclusions:* Packaging, biocompatibility and corrosion tests were performed according to ISO 11607-1 and ISO 11607-2, ISO 10993 and ASTM F2129, respectively.

All bench tests performed in accordance with ASTM standards and previously presented in EasyClip® and EasyClip® Xpress, K122113 and K162321, respectively, remains true and accurate.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the equivalent materials and processes as the predicate devices. Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that:

• any differences do not raise new questions of safety and effectiveness as established with performance testing; and

• the subject devices are substantially equivalent to the legally marketed predicate devices.