March 5, 2019

Stryker
Hans Geiger
Senior Regulatory Affairs Specialist
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K183172
Trade/Device Name: Stryker SternalPlate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 17, 2019
Received: January 22, 2019

Dear Mr. Geiger:

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,

Laurence D. Coyne -S

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)*
K183172

Device Name
Stryker SternalPlate System

Indications for Use *(Describe)*
The SternalPlate system is indicated for use in stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal fracture(s), and sternal reconstructive surgical procedures to promote bony fusion.

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

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER [§807.92(a)(1)]

510(k) Owner:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 79111 Freiburg, Germany
Submitter/ Contact Person:	Hans M. Geiger Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Suite 200 Portage, MI 49002 Phone: 269-389-2323 Fax: 877-648-7114
Date prepared:	February 28, 2019

II. DEVICE [§807.92(a)(2)]

Trade Name:	Stryker SternalPlate System
Common or Usual name:	Bone Plate and Screws
Classification name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulation Number:	21 CFR § 888.3030
Regulatory Class:	Class II
Product Code:	HRS

III. PREDICATE DEVICE [§807.92(a)(3)]

Biomet Microfixation Sternal Closure System – K121302
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION [§807.92(a)(4)]

The Subject Device System contains various plates with different shapes which allow for intraoperative contouring and cutting of the plates as well as for postoperative emergent cutting. The plates accept screws with a diameter of 2.3mm and 2.7mm. The Subject Device System consists of self-drilling locking screws and self-tapping locking screws. The self-drilling locking screws are designed to allow for screw fixation with no pre-drilling. The self-tapping locking screws require pre-drilling before insertion.

The Subject Device plates and screws are provided non-sterile and are for single use only.

V. INDICATIONS FOR USE [§807.92(a)(5)]

TABLE 1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	**Predicate – K121302**
Indications for Use	The SternalPlate System is indicated for use in stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal fracture(s), and sternal reconstructive surgical procedures to promote bony fusion.	The Biomet Microfixation Sternal Closure System is indicated for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion.

The Indications for Use statement of the Subject Device falls within the scope of the broader Indications statement of the Predicate Device. The differences in the Indications statement for the proposed device in comparison to the predicate does not constitute a new indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [§807.92(a)(6)]

The Subject Device is compared to its predicate devices for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological and Operational Characteristics

A. Principle of Operation

The basic operational principle of the Subject Device, as well as the Predicate Device is for sternal fixation following sternotomy and sternal reconstructive surgical procedures to promote bony fusion. The method of site preparation and fixation is the same for both the Subject and Predicate Device.

B. Technological and Operational Characteristics

At a high level, the Subject Device and Predicate Device are based on the following technological elements:

- Material: Both the Subject Device and Predicate Device are made of biocompatible titanium according to standards.
- Mode of fixation: Implant fixation with screws of the Subject Device is the same as the Predicate Device.
- Equivalent plate design: The Subject Device has equivalent plate designs compared to the Predicate Device consisting of screw holes connected via bars.
- Similar Dimension: The Subject Device System contains various plates and screws of different shapes which are in the same range as the screws and plates of the Predicate Device.

Overall these changes do not alter the Subject Device significantly and do not represent a new worst case in design.

VII. PERFORMANCE DATA [§807.92(b)(1)]

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

Biocompatibility Assessment

For assessment of biocompatibility for the Subject Device System, the following documents were used for guidance:

• ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

• FDA guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process,” issued June 16, 2016.

Based on the guidance stated above, the plates and screws of the Subject Device System are categorized as implants, with permanent (>30d) contact in a bone region. The instruments of the Subject Device are categorized as instruments with limited contact (<24h) and instruments without contact.

The Subject Device implants are made of titanium according to international standards ASTM F67 / ASTM F136 and have a long history of use in the same indications (ISO 10993-1, Section 4.1). Furthermore, the ASTM standards establish that biological reactivity is acceptable in the clinical conditions of use.

During the biocompatibility assessment of the implants, reference devices K151387 (screws) and K014263 (plates) have been identified which are equivalent to the subject device in terms of biocompatibility. Therefore, no further biocompatibility testing was necessary.

Performance Bench Testing

The following performance tests were performed in support of the substantial equivalence determination:

- Cleaning Validation
- Sterilization Validation
- Biocompatibility
- Product Design Validation
- MR Compatibility
- Screw Performance
- Plate Performance

The Subject Device met all pre-defined acceptance criteria and standards and was found to not represent a new worst case. Overall, the results of the performance bench tests support the substantial equivalence of the Subject device.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing [§807.92(b)(2)]

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS [§807.92(b)(3)]

The results of the non-clinical data demonstrate the Subject Device will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.92 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.