December 11, 2024

Stryker Leibinger GmbH & Co. KG
Amelia Kesti
Staff Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, D-79111
Germany

Re: K243491
Trade/Device Name: SternalPlate Expansion
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: November 8, 2024
Received: November 12, 2024

Dear Amelia Kesti:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K243491

Device Name

SternalPlate Expansion

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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."*

# 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<br>Boetzinger Strasse 41<br>D-79111 Freiburg, Germany |
| Submitter/ Contact Person: | Amelia Kesti<br>Staff Regulatory Affairs Specialist<br>Stryker Craniomaxillofacial (CMF)<br>1941 Stryker Way<br>Portage, MI 49002<br><br>Phone: 269-330-5919 |
| Date prepared: | 11/08/2024 |


II. DEVICE [§807.92(a)(2)]

| | |
|---|---|
| Trade Name: | SternalPlate Expansion |
| Abbreviated Name: | SternalPlate Expansion |
| Common or Usual Name: | Plate, Fixation, Bone |
| Device: | SternalPlate Expansion |
| Classification Name & Regulation Description: | Plate, Fixation, Bone; per 21 CFR §888.3030 |
| Regulation Medical Specialty & Review Panel: | Office of Product Evaluation and Quality, Office of Orthopedic Devices, Division of Restorative, Repair and Trauma, Devices, DHT6C |
| Product Code: | HRS |
| Regulatory Device Class: | Class II |

*Note the company Stryker or legacy name Stryker Leibinger precedes the product/trade name and predicate device in some documentation.

III. PREDICATE DEVICE [§807.92(a)(3)]

A. Predicate Devices: The predicate devices for this Special 510(k) are:

1. Primary Predicate: Stryker SternalPlate System – K183172

i. Submission Branch of Predicate Device- Division of Orthopedic Devices, Office of Device Evaluation, Center for Devices and Radiological Health

2. Additional Predicate: DePuy Synthes Sternal Fixation System – K190963

i. Submission Branch of Predicate Device- Division of Restorative, Repair and Trauma Devices, Office of Orthopedic Devices, office of Product Evaluation and Quality, Center for Devices and Radiological Health

3. Additional Predicate: KLS Martin Thoracic Plating System – K153482

i. Submission Branch of Predicate Device- Division of Orthopedic Devices, Office of Device Evaluation, Center for Devices and Radiological Health

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

A. Submission Branch of Subject Device: Office of Orthopedic Devices, Office of Product Evaluation and Quality, Division of Stereotaxic, Trauma, and Restorative Devices, DHT6C

B. Subject Device: SternalPlate Expansion
This Special 510(k) is submitted to evaluate the modifications to the Predicate Device plates resulting in the Subject Device plates. There have been no changes to the previously cleared plates and screws cleared in K183172, this submission is only for the addition of the four new Subject Device plates.

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

The Predicate and Subject devices are both intended for use in the anterior chest wall. The anterior chest wall includes both the sternum and the anterior ribs. The Subject Device does not change the existing indications for use for the Stryker SternalPlate System. The new plates fall within the scope of the existing indications in the anterior chest wall without alteration.

**TABLE 5-1: COMPARISON OF INDICATIONS FOR USE**

| Aspect | Subject Device | Primary Predicate Device (K183172) |
|---|---|---|
| Intended Use/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 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. |

Please note that this 510(k) lists several additional Predicate devices, however, these additional Predicate devices were used for testing and not overall substantial equivalence evaluation.

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

The Subject Device is compared to its Predicate Devices for substantial equivalence of technological characteristics based on the following criteria:

A. Principles of Operation
B. Technological Characteristics

### A. Principles of Operation / Operating Principle

The basic operating principle of the Subject Device remains the same as the Predicate Device. The basic operating principle of the Subject Device, as well as the Predicate Device is fixation and stabilization of the anterior chest wall. The method of site preparation and fixation is the same for both the Subject and Predicate Device.
The fundamental scientific technology of the Subject Device has not changed. This is because the principle of operation, the mechanism of action, the intended use, and the materials of construction have not changed as a result of the device modifications.

### B. Technological Characteristics

There have been no changes to the previously cleared plates and screws cleared in K183172, this Special 510(k) is only for the addition of the four new Subject Device plates. The four Subject Device plates include T-Plates and Transverse Plates. Both Subject Device variants, the T-Plates and Transverse Plates, are geometrically derived from the following Predicate Device plates: the Ladder Plate Narrow (Ref# 4740006) and the Straight 24-hole Plate (Ref# 4740012).

The Subject Device plates therefore have the same features, the same tolerances, and are made from the same material as the Predicate Device plates. Furthermore, the Subject

Device plates are manufactured with the same manufacturing process as the Predicate Device plates.

## VI. PERFORMANCE DATA [§807.92(b)(7)]

Appropriate strength and stiffness of the new plates are confirmed by the Verification and Validation testing, and no new questions of safety or effectiveness arise as a result of the testing.

The subject devices have been evaluated for Biocompatibility per the requirements of ISO 10993-1:2018 and in alignment with corresponding FDA guidance. This evaluation has concluded that no new or increased biocompatibility risks are associated with the subject device.

Sterility testing was not required as a basis for substantial equivalence. There is no change in the subject device material, manufacturing process, duration or location of contact, or reprocessing methods.

### Performance Bench Testing

As the Subject Device plates, unlike the original Predicate Device plates, can be fixated laterally to the sternum, additional Verification and Validation data was needed for the Subject Device. This submission uses well established test methods used in prior submissions including K183172 previously reviewed by the FDA. These tests are summarized within the Special 510(k).

Plate stiffness and strength were tested in comparison to the Additional Predicate Devices DePuy Synthes Sternal Fixation System (K190963) and KLS Martin Thoracic Plating System (K153482). The Subject Device plates met all acceptance criteria as compared to the Additional Predicate Devices. The results of this testing show that the Subject Device plates do not raise new questions in terms of safety and effectiveness when compared to the Predicate Device plates.

### 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.

## VII. CONCLUSIONS [§807.92(b)(3)]

In summary, the Subject Device is substantially equivalent to its Predicate Device. The Subject Device's features, tolerances, material, mechanism of action, intended use, and

manufacturing process are the same as the Predicate Device. The Subject Device's intended use is unchanged compared to the Predicate Device. Appropriate strength and stiffness of the new plates are confirmed by the Verification and Validation testing, and no new questions of safety or effectiveness arise as a result of the testing. There are no new questions of safety or effectiveness regarding the modifications to the Predicate Device plates resulting in the four Subject Device plates. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence to the predicate devices.