July 1, 2026

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

Re: K261054
Trade/Device Name: RibPlate 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, HWC
Dated: June 3, 2026
Received: June 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261054

Please provide the device trade name(s).

RibPlate System

Please provide your Indications for Use below.

The RibPlate System is intended for use in the stabilization and fixation of fractures and reconstructions in the chest wall, including sternal reconstructive surgical procedures to promote bony fusion. The RibPlate system can be used in normal and poor bone.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K261054
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 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Amelia Kesti Senior Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial (CMF) 1941 Stryker Way Portage, MI 49002 Phone: 269-330-5919
Date prepared:	07/01/2026

II. DEVICE [§807.92(a)(2)]

Trade Name:	RibPlate System
Abbreviated Name:	RibPlate System
Common or Usual Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Device:	RibPlate System
Classification Name & Regulation Description:	Plate, Fixation, Bone; per 21 CFR §888.3030 Single/multiple component metallic bone fixation appliances and accessories Screw, Fixation, Bone; per 21 CFR §888.3040 Smooth or threaded metallic bone fixation fastener
Regulation Medical Specialty & Review Panel:	Office of Orthopedic Devices, Office of Product Evaluation and Quality, Division of Stereotaxic, Trauma, and Restorative Devices, DHT6C
Product Code:	HRS (Primary), HWC
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 Traditional 510(k) are:

1. Primary Predicate: Biomet Microfixation RibFix Blu Thoracic Fixation System – K212608

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

2. 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

3. Additional Predicate: DePuy Synthes MatrixRIB Fixation System – K161590

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

Biomet Microfixation RibFix Blu Thoracic Fixation System (K212608) was selected as the Primary Predicate for substantial equivalence in this submission. Additional FDA cleared predicate devices were referenced to support evaluation of performance characteristics.

We are only utilizing the Primary Predicate, Biomet Microfixation RibFix Blu Thoracic Fixation System (K212608), for our substantial equivalence comparison.

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: RibPlate System
This Traditional 510(k) is submitted for the Stryker RibPlate System. The Subject Device contains various commercially pure titanium or titanium alloy plates and screws for use in the chest wall.

V. INDICATIONS FOR USE [§807.92(a)(5)]
The wording of the Indications for Use statements for the Predicate device in comparison to the Subject is fundamentally equivalent. See Table 5-1 below.

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

Aspect	Subject Device	Primary Predicate Device (K212608)
Intended Use/Indications for Use	The RibPlate system is indicated for use in the stabilization and fixation of fractures and reconstructions in the chest wall, including sternal reconstructive surgical procedures to promote bony fusion. The RibPlate system can be used in normal and poor bone.	The Biomet Microfixation RibFix Blu Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, rib fractures associated with flail chest, or planned osteotomies. The system may be used in normal and poor bone to promote union.

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 is the same as the Predicate Device. The basic operating principle of the Subject Device, as well as the Predicate Device is the stabilization and fixation of fractures and reconstruction in the chest wall using titanium plates and screws that lock into each other.

B. Technological Characteristics

The operating principle, fixation method, material, sterility and sterilization method, and patient population are identical between Subject Device and Predicate Device Systems. The dimensions of the Subject Device plates and screws are similar to the Predicate Device in size and screw/plate interface.

VI. PERFORMANCE DATA [§807.92(b)(1 and 2)]

Biocompatibility

The Subject Devices have been evaluated per the requirements of ISO 10993-1:2018 Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process and in alignment with FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – part 1: Evaluation and testing with a risk management process Issued September 4, 2020. This evaluation has concluded that no new or increased biocompatibility risks are associated with the Subject Device.

Reprocessing and Sterility

The reprocessing instructions (cleaning, disinfection, and sterilization) for the Stryker RibPlate system (Subject Device) were validated to ensure the device conforms to the defined user needs and Intended Use/Indication for Use. The sterility testing was conducted according to BS ISO 17664-1, ISO 17665, AAMI TIR12, AAMI TIR39, ANSI/AAMI ST77, ANSI/AAMI ST79 and FDA guidance using a steam autoclave.

The Subject Device is provided non-sterile and is intended to be sterilized by the end-user via steam sterilization methods.

Performance Bench Testing

All Verification and Validation (V&V) tests, which were identified in the risk analysis, met their respective acceptance criteria as compared to the Predicate Devices. These V&V tests included static 4-point-bending, dynamic 4-point-bending, pull-out, insertion and removal, shear-off, profile height, locking torque to failure, locking removal torque, self-retention, and end-user tests.

The results of these tests support the fact that the Subject Device fulfils the design inputs claimed in the Design Input / Output Verification and Validation (DIOVV) document. The results of this testing show that Subject Device is substantially equivalent to the Predicate Devices.

An assessment regarding magnetic resonance (MR) compatibility for the Subject Device was conducted. Magnetically induced displacement force, magnetically induced torque, and MR image artifact were evaluated through comparison to previously tested reference devices, while RF-induced heating was evaluated using computational modeling and simulation. Based on a worst-case analysis using computational modeling and scientific rationales, along with previously conducted testing on a Reference Device, the Subject Device was determined to be MR Conditional. The assessment was conducted per FDA Guidance, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, FDA, 2023" and utilized methods described in ASTM F2182, ASTM F2052, ASTM F2213, and ASTM F2119.

Animal Testing

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

Clinical Testing

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

VII. CONCLUSIONS [§807.92(b)(3)]

The Intended Use and Technological Characteristics comparisons provide evidence to prove substantial equivalence between the Subject and Predicate Device. There are no substantial differences between the devices. Therefore, Subject Device is substantially

equivalent to the Predicate Device with respect to Intended Use, General Characteristics, and Technological Characteristics.