February 26, 2026

Globus Medical, Inc
Krunal Shah
Staff Specialist, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K252166
Trade/Device Name: RIB LINK™ Fixation 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: January 22, 2026
Received: January 23, 2026

Dear Krunal Shah:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Thomas Mcnamara -S

For: 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. | K252166 |

Please provide the device trade name(s).

RIB LINK™ Fixation System

Please provide your Indications for Use below.

The RIB LINK™ Fixation System is indicated for use in the stabilization, fixation, and reconstruction of rib fractures, fusions, osteotomies, resections, including spanning gaps and/or defects, and chest wall deformities including rib hump deformity. These implants are indicated for use in skeletally mature patients with normal or osteoporotic bone for chest wall fixation.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary: RIB LINK™ Fixation System

**Company:** Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

**Contact:** Krunal Shah
Staff Specialist, Regulatory Affairs

**Secondary Contact**: Jennifer Antonacci, PhD
Director, Regulatory Affairs

**Date Prepared:** February 26, 2026

**Device Name:** RIB LINK™ Fixation System

**Common Name:** Plate, Fixation, Bone
Screw, Fixation, Bone

**Classification:** Per 21 CFR as follows:
§888.3030: Single/Multiple component Metallic Bone Fixation Appliances and Accessories

§888.3040: Smooth or threaded metallic bone fixation fastener
Product Code(s): HRS, HWC
Regulatory Class: II, Panel Code: 87

**Primary Predicate:** Depuy Synthes MatrixRIB Fixation System (K190409)

**Additional Predicates:** Biomet MicroFixation RibFix Blu Thoracic Fixation System (K212608)

**Reference Devices:** REVERE® 4.5 Stabilization System (K113395)
CREO® Stabilization System (K182375)
ANTHEM™ Fracture System (K163361)

**Purpose:**
The purpose of this submission is to request clearance for the RIB LINK™ Fixation System.

**Device Description:**
The RIB LINK™ Fixation System includes a variety of plates, rods, and screws intended for use in rib fixation and stabilization applications. The implants are available in various sizes and styles and can be assembled in multiple construct configurations to accommodate varying patient anatomy. The constructs can be

surgically positioned across the external surface of the ribs. RIB LINK™ implants are manufactured from titanium alloy as specified in ASTM F136.

**Indications for Use:**
The RIB LINK™ Fixation System is indicated for use in the stabilization, fixation, and reconstruction of rib fractures, fusions, osteotomies, resections, including spanning gaps and/or defects, and chest wall deformities including rib hump deformity. These implants are indicated for use in skeletally mature patients with normal or osteoporotic bone for chest wall fixation.

**Performance Data:**
Performance of the RIB LINK™ constructs was evaluated in static and fatigue performance with ASTM F1717, with modifications for rib fixation applications. Screw testing was conducted in accordance with ASTM F543. Performance data demonstrates substantial equivalence to the predicate devices.

**Comparison of Indications and Technological Characteristics:**
Subject implants have similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

The subject device differs from the predicate with the added rib hump deformity indication for use. Posterior thorax reconstruction presents risks similar to lateral and anterior thorax procedures. The screws and some plates are comparable to the predicate devices. The system includes rods that connect different plate types along the ribs, allowing each plate to align with the curvature of the ribs for posterior thorax use. When spanning gaps, some of the subject devices permit 4 cortices of fixation at each end, equal to or less than the predicate devices.

**Conclusions:**
RIB LINK™ Fixation System implants have been found to be substantially equivalent to the predicate devices with respect to technological characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject implants to the predicate devices.