



September 23, 2026

Costa Surgical, Inc.
Nick Slater
CEO
3225 N. Colorado St.
Chandler, Arizona 85225

Re: K261892

Trade/Device Name: ProRib 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, HTN

Dated: June 5, 2026

Received: June 5, 2026

Dear Nick Slater:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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.

K261892

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Please provide the device trade name(s).

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ProRib Fixation System

Please provide your Indications for Use below.

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The ProRib Fixation System extrathoracic plates and locking screws are 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.

The ProRib Fixation System intrathoracic implants are indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic 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](#))

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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)

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510(k) Summary K261892

Device Trade Name: ProRib™ Fixation System

Manufacturer: Costa Surgical
3225 N. Colorado St
Chandler, AZ 85225

Primary Contact: Nick Slater
CEO, Costa Surgical
570-713-9227

Prepared by: Nick Slater
CEO, Costa Surgical
3225 N. Colorado St
Chandler, AZ 85225
570-713-9227

Date Prepared: 05 June 2026

Classifications: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Class: II

Product Codes: HRS, HWC, HTN

Primary Predicate: K203474 - Biomet Microfixation RibFix Advantage System

Additional Predicate: K212608 - Biomet Microfixation RibFix Blu Thoracic Fixation System
K222397 - KLS Martin L1 PEEK Rib Fixation System

Reference Devices:

- K153482 – KLS Martin Thoracic Plating System
- K232515 - Able Medical Valkyrie Rib System
- K081623 - Synthes MatrixRib Fixation System

Indications For Use:

The ProRib Fixation System extrathoracic plates and locking screws are 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.

The ProRib Fixation System intrathoracic implants are indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Device Description:

ProRib Fixation System consists of single use implants for fixation of broken ribs both intra- and extra-thoracically. The system includes metallic and polymeric plates and metallic locking screws for extrathoracic fixation, as well as metallic and polymeric bridges, metallic cap screws, washers, and supplemental posts for intrathoracic fixation. The system includes both single-use and reusable general instruments for the proper introduction and placement of the implants.

Predicate Device:

Costa Surgical submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, ProRib Fixation System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate:

K203474 - Biomet Microfixation RibFix Advantage System

Additional Predicate:

K212608 - Biomet Microfixation RibFix Blu Thoracic Fixation System

Performance Testing Summary:

Performance testing was conducted to evaluate the mechanical performance of the subject device. Testing includes:

- ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws
- ASTM F1717-21 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model - adapted for rib fixation
- ASTM F2052-21: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213-25: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119-24: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants



All testing satisfied the applicable acceptance criteria, confirming that the device performs as intended and is comparable to the predicate and reference devices.

Substantial Equivalence:

The ProRib Fixation System demonstrates:

- Indications for use that are identical to those of the predicate device
- Design and technological characteristics that are equivalent to predicates and reference devices
- Materials that are identical to those of the predicate and reference devices
- Performance data establishing equivalence to achieve the intended use of the device.

The ProRib Fixation System is substantially equivalent to the identified predicate and reference devices.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. ProRib Fixation System is substantially equivalent to the predicate devices.