April 24, 2026

Chest Wall Innovations, Inc.
% Jennifer Palinchik
Owner & CEO
Sagemar Medical, LLC
Contact Address

Re: K260411
Trade/Device Name: PC Fix 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, HTN
Dated: April 9, 2026
Received: April 9, 2026

Dear Jennifer Palinchik:

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.	K260411

Please provide the device trade name(s).

PC Fix System

Please provide your Indications for Use below.

The PC Fix System is 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)

510(k) Summary

04/08/2026

Submitter:
Chest Wall Innovations, Inc.
710 W. Chocolate Ave, Suite 1061
Hershey, PA 17033 USA

Official Correspondent:
Jennifer Palinchik
(440) 935-3282

Device Trade Name:	PC Fix System
Device:	Plate, Fixation, Bone Washer, Bolt Nut
Device Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulation Number:	21 CFR 888.3030
Regulatory Class:	Class II
Product Code:	HRS, HTN
Review Panel:	Orthopedic
Primary Predicate:	Zimmer Biomet RibFix Advantage System (K203474)
Reference Devices:	Riverpoint Medical RibFix Titan Fixation System (K241282) Able Medical Valkyrie Thoracic Fixation System (K202889)

Device Description:

The Chest Wall Innovations PC Fix System consists of titanium and PEEK rib plates and a post-and-cap fixation construct intended for stabilization and fixation of rib fractures and osteotomies. The system includes:

- Standard fixation plates with slots, holes, and bone-facing anchoring teeth.
- Locking posts designed to support plate positioning and stabilization.
- Locking caps that engage the posts to secure the plate to the rib.
- Reusable stainless-steel instruments manufactured from medical-grade stainless steels conforming to ASTM F899

All implants are provided non-sterile and must be sterilized by the end user prior to implantation. Instruments are reusable and require cleaning and sterilization prior to each use.

Intended Use / Indications for Use:

The PC Fix System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Substantial Equivalence Conclusion:

The PC Fix System demonstrates:

- Indications for use that are identical to those of the predicate device
- Design and technological characteristics that are equivalent to the predicate and reference devices
- Materials that are identical to those used in the predicate and reference devices
- Performance data confirming that any differences do not raise new questions of safety or effectiveness

Based on these factors, the PC Fix System is substantially equivalent to the identified predicate and reference devices.

Non-Clinical Testing:

Non-clinical testing was conducted to evaluate the mechanical performance of the subject device. Testing includes:

- Static and Dynamic ASTM F382 Standard Specification and Test Method for Metallic Bone Plates
- Static and Dynamic ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model (adapted for rib fixation)

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

Clinical Testing:

Clinical testing was not required to support a substantial equivalence determination for the PC Fix System.

Conclusion:

The device's mechanical performance, materials, indications, and function are comparable to the predicate device and reference devices, supporting a determination of substantial equivalence.