January 28, 2026

4Web Medical
Jonathan Hires
Director, Product Development
2801 Network Blvd.
Suite 620
Frisco, Texas 75034

Re: K252834
Trade/Device Name: Sacroiliac Joint Truss System (SJTS)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC
Dated: September 5, 2025
Received: December 29, 2025

Dear Jonathan Hires:

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,

STEPHANIE SMITH -S

For Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*

K252834

Device Name

Sacroiliac Joint Truss System (SJTS)

Indications for Use *(Describe)*

The Sacroiliac Joint Truss System is indicated for sacroiliac joint fusion for:

• Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
• Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The Sacroiliac Joint Truss System is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

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.

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510(k) Summary

Date Prepared: December 29th, 2025
Contact: Jonathan Hires, Director of Product Development
4Web Medical
2801 Network Blvd., Suite 620
Frisco, TX 75034
Phone: (800) 285-7090
Fax: 972-488-1816

Trade Name: Sacroiliac Joint Truss System (SJTS)
Product Class: Class II
Classification: 21 CFR §888.3040
Common Name: Sacroiliac Joint Fixation
Product Codes: OUR, HWC

Predicate Device(s): The primary predicate device is the SI-BONE iFuse-TORQ Implant System (K222605). The additional predicate device is the SI-BONE iFuse Bedrock Granite Implant System (K220195). Reference predicates for this submission are the 4Web Medical Lateral Spine Truss System Plating Solution (K203065).

Device Description: The SJTS is a comprehensive surgical solution for sacroiliac joint fusion procedures. The system consists of an instrument set and a wide range of threaded implants. All screws in the 4Web SJTS are cannulated, fenestrated, and made of medical grade Ti6Al4V alloy. The screws come in two distinct sterile implant offerings: a fully threaded screw with compression threads on the proximal head and a partially threaded lag screw with an accompanying washer. The implant offering includes a choice of three different diameters with a variety of lengths to accommodate the patient's anatomy.

The SJTS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Indications for Use:
The Sacroiliac Joint Truss System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The Sacroiliac Joint Truss System is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

Technological Characteristics Comparison:

The subject device and the primary predicate device have similar technological characteristics in terms of intended use, materials, design, function, and performance. The minor differences do not raise any new issues of safety and effectiveness. The subject device when compared to the reference predicate does not introduce any new questions of safety and effectiveness in terms of adoption into the 4Web Medical cleaning and sterilization family.

Performance Standards:

The 4Web Medical Sacroiliac Joint Truss System has been tested per the following test modes:

- Static Cantilever Bending per ASTM F3574
- Dynamic Cantilever Bending per ASTM F3574
- Axial Pullout per ASTM F3574
- Static Torsion per ASTM F3574
- Driving Torque per ASTM F3574
- MR Image Artifact per ASTM F2119
- MR induced Heating per ASTM F2182
- MR Induced Torque per ASTM F2213
- MR Induced Displacement Force per ASTM F2051

The results of this non-clinical testing show that the strength of the Sacroiliac Joint Truss System implants is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Conclusion:

4Web Medical concludes that the Sacroiliac Joint Truss System implants are substantially equivalent to the predicate devices and raise no new questions of safety and effectiveness.