November 1, 2024

4WEB Medical, Inc.
% Richard Jansen
Consultant
Silver Pine Consulting
3851 Mossy Oak Drive
Fort Myers, Florida 33905

Re: K240388
Trade/Device Name: Osteotomy Truss System (OTS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 1, 2024
Received: October 1, 2024

Dear Richard Jansen:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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

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)*

K240388

Device Name

Osteotomy Truss System (OTS)

Indications for Use *(Describe)*

The Osteotomy Truss System (OTS) is intended to be used for internal bone fixation for bone fractures or osteotomies in the foot, such as:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal/Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies

The device is intended for use with supplemental fixation.

The Osteotomy Truss System is not intended for use in the spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: September 30th, 2024
Contact: Jessee Hunt, President
4WEB, Inc.
2801 Network Blvd., Suite 620
Frisco, TX 75034
Phone: (800) 285-7090
Fax: 972-488-1816

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade Name: Osteotomy Truss System (OTS)
Product Class: Class II
Classification: 21 CFR §888.3030
Common Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Product Codes: HRS
Panel Code: 87

Purpose:
The purpose of this submission is to update the Osteotomy Truss System (OTS) implant offering.

Indications for Use:
The Osteotomy Truss System (OTS) is intended to be used for internal bone fixation for bone fractures or osteotomies in the foot, such as:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal/Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies

The device is intended for use with supplemental fixation.

The Osteotomy Truss System is not intended for use in the spine.

Device Description:
The Osteotomy Truss System (OTS) consists of five implant designs in a variety of footprints and implant height options to accommodate the patient's anatomy. It is intended to be used with supplemental fixation.

The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface roughness. The implant is made from Ti6Al4V alloy.

Predicate Device(s):
The primary predicate device is the 4WEB Medical Osteotomy Truss System (K220463).

Performance Standards:
Engineering analysis, static axial compression testing per ASTM F2077, and dynamic axial compression testing per ASTM F2077 demonstrated that the product line extension for the Osteotomy Truss System (OTS) does not introduce a new worst-case compared to the previously cleared 4WEB Osteotomy Truss System devices for mechanical properties of the device.

Performance testing has been completed per the following standards for the combined Osteotomy Truss System (OTS):

- Static axial compression per ASTM F2077
- Dynamic axial compression fatigue per ASTM F2077
- Expulsion testing per ASTM F-04.25.02.02
- MR image artifact per ASTM F2119
- MR induced heating per ASTM F2182
- MR induced torque per ASTM F2213
- MR induced displacement force per ASTM F2052

The results of this non-clinical testing show that the strength of the OTS Device is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Technological Characteristics:
4WEB, Inc. has compared these devices to the previously cleared predicate devices in regard to indications for use, materials, function, sizes and simulated testing. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusion:
4WEB, Inc. concludes that the OTS device is substantially equivalent to the predicate devices and raise no new questions of safety or effectiveness.