4WEB Medical, Inc.
% Kathy Herzog
Regulatory Consultant
DuVal & Associates, P.A.
1820 Medical Arts Building 825 Nicollet Mall
Minneapolis, Minnesota 55402

March 21, 2024

Re: K230088
Trade/Device Name: Ankle Truss System (ATS)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: SAI, HSB
Dated: March 19, 2024
Received: March 20, 2024

Dear Kathy Herzog:

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.

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2024.03.21 15:03:45 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230088

Device Name
Ankle Truss System (ATS)

Indications for Use *(Describe)*

The 4WEB Medical Ankle Truss System (ATS) is for use as an accessory to the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk for loss of limb. The ATS is not intended for standalone use.

The anatomical landmarks necessary for the design and creation of ATS devices that are patient matched must be present and identifiable on appropriate radiography scans. The ATS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

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.

510(k) Summary

Date Prepared: March 21, 2024

Contact: Jarod Oldham, VP of Quality and Regulatory
4WEB Medical, Inc.
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Regulatory Contact: Kathy Herzog, Sr. Regulatory, Quality, & Compliance Consultant
DuVal & Associates, PA
herzog@duvalfdalaw.com

Trade Name: Ankle Truss System (ATS)
Product Class: Class II
Classification: 21 CFR §888.3020
Common Name: Rod, Fixation, Intramedullary and Accessories
Product Code: SAI
Secondary Product Code: HSB

Predicate Device(s):
The primary predicate device is the Stryker Valor Hindfoot Fusion Nail (K090857). An additional predicate is the Stryker T2 Ankle Arthrodesis Nail (K200880). A reference device is the 4WEB Medical Lateral Spine Truss System – Interbody Fusion Device (K211388).

Device Description:
The 4WEB Medical Ankle Truss System (ATS) is a permanently implanted device intended to provide mechanical support as an accessory to a tibiotalocalcaneal nail intended to fuse the tibiotalocalcaneal joint in a salvage procedure following a failed ankle arthrodesis or a failed ankle arthroplasty for patients at risk for loss of limb. ATS devices are titanium alloy (Ti6Al4V) structures in spherical or cuboidal configurations. The ATS device has an open architecture truss design that is designed to provide structural support with open space throughout the implant to allow fusion. ATS devices are intended for use with the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a tibiotalocalcaneal (TTC) fusion system.

Indications for Use:
The 4WEB Medical Ankle Truss System (ATS) is for use as an accessory to the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk for loss of limb. The ATS is not intended for standalone use.

The anatomical landmarks necessary for the design and creation of ATS devices that are patient matched must be present and identifiable on appropriate radiography scans. The ATS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Subject and Predicate Device Comparison
Both the subject and predicate devices have the same intended use for tibiotalocalcaneal (TTC) fusion. The indications for use of the ATS are a subset of the indications for use for the predicate Stryker Valor Hindfoot Fusion Nail, K090857.

The technological characteristics of the ATS device differ from the predicate device. The materials, truss design, and manufacturing of the ATS are similar to the reference device (K211388). Both the subject device and reference device are made of titanium alloy (Ti6Al4V) and are manufactured using an identical additive manufacturing technique.

Non-Clinical Performance Evaluation
The following non-clinical performance testing has been completed on the subject device:

- Static and dynamic testing per ASTM F2077 (With and Without an IM Nail) followed by testing per ASTM F1264
- Corrosion Assessment
- Wear Assessment

Clinical Performance Evaluation
4WEB Medical completed a retrospective, single arm, multi-center evaluation of the ATS device. Control treatments were an IM nail for TTC fusion for failed total ankle or failed ankle arthrodesis patients. Effectiveness endpoints included fusion, pain, and functional outcomes for the subject and control treatments. Safety outcomes included analysis of device and procedure related adverse events and rates of subsequent secondary surgical intervention (SSSI) for the subject and control treatments.

Conclusion
The nonclinical and clinical performance testing demonstrate that the subject device is substantially equivalent to the predicate device, Stryker Valor Hindfoot Fusion Nail (K090857), when used as intended.