July 23, 2019

4WEB, Inc.
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
3851 Mossy Oak Drive
Ft. Myers, Florida 33905

Re: K190926
Trade/Device Name: Hammertoe Truss System (HTS)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: July 3, 2019
Received: July 5, 2019

Dear Dr. 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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ronald P. Jean, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190926

Device Name
Hammertoe Truss System (HTS)

Indications for Use *(Describe)*
The Hammertoe Truss System (HTS) is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the Hammertoe Truss System (HTS) can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

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:	April 9, 2019
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:	Hammertoe Truss System (HTS)
Product Class:	Class II
Classification:	21 CFR §888.3040
Common Name:	Smooth or threaded metallic bone fixation fastener
Product Codes:	HTY
Panel Code:	87

Indications for Use:

The Hammertoe Truss System (HTS) is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the Hammertoe Truss System (HTS) can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

Device Description:

The 4WEB HTS implants consists of a series of titanium implants that are designed to provide stability and fixation of the lesser toes in the foot. The 4WEB HTS implants have proximal and distal fixation features to provide structural support and will be offered in multiple sizes to accommodate various patients' anatomy. The implants are manufactured from Ti6Al4V alloy. Each implant is available in a sterile/packaged form.

Predicate Device(s):

The primary predicate device is the Additive Orthopaedics Hammertoe Correction System (K160264). Additional predicates include the Wright Medical PRO-TOE Hammertoe Fixation System (K151838).

Performance Standards:

Performance testing has been completed per the following standards:
ASTM F1264 – Static and Dynamic 3-Point Bend and Torque to Failure
ASTM F543 – Axial Push Out

MR Conditional testing listed below is from the primary predicate device, the 4WEB CSTS Cervical Spine Truss System (K173159). The Hammertoe Truss System does not present a new worst case.
ASTM F2119 – MR Image Artifact
ASTM F2052 – MR Induced Displacement Force
ASTM F2213 – MR Induced Torque
ASTM F2182 – MR Induces Heating

Technological Characteristics:

4Web Medical, Inc. has compared this device to the previously cleared predicate devices in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusion:

4WEB Medical, Inc. concludes that the Hammertoe Truss System is substantially equivalent to the predicate devices.