February 22, 2018

4Web, Inc.
% Rich Jansen
Consultant
Silver Pine Consulting, LLC.
1142 26 1/2 Ave
Cumberland, Wisconsin 54829

Re: K172294
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: January 10, 2018
Received: January 12, 2018

Dear Rich 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K172294

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 HalluxValgus
-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

These devices are intended to be used 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.

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510(k) Summary

Date Prepared:	February 16, 2018
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 Single/multiple component metallic bone fixation appliances and accessories
Common Name:	Bone Wedge
Product Codes:	HRS
Panel Code:	87

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

These devices are intended to be used with supplemental fixation.
The Osteotomy Truss System is not intended for use in the spine.

Device Description:
The Osteotomy Truss System is a titanium alloy implant used for correction of small bones in the foot. It is offered in three footprints and multiple sizes for each footprint with varying widths and thicknesses to accommodate a variety of small bone applications. Each device uses the 4WEB truss system of architecture. Implants are made from medical grade titanium allow (6Al4V-ELI) per ASTM F-136/ISO 5832-3.

Predicate Device(s):
The Osteotomy Truss System is substantially equivalent to the primary predicate, which is the previously cleared 4WEB Osteotomy Bone Wedge (K130185). An additional predicate device is K152062, BIOFOAM Bone Wedge.

Non-clinical testing:
ASTM F2077 – Static and dynamic axial compression
ASTM F2119 – MR Image Artifact
ASTM F2052 – MR Induced Displacement Force
ASTM F2213 – MR Induced Torque
ASTM F2182 – MR Induces Heating
Expulsion testing

The results indicate that the Osteotomy Truss System is substantially equivalent to the predicate device and is adequate for the intended use.

Technological Characteristics:

4WEB, Inc. has compared these changes 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, Inc. concludes that the OTS devices are substantially equivalent to the predicate devices.