February 2, 2023

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

Re: K223362
Trade/Device Name: Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: December 13, 2022
Received: December 14, 2022

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 (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,

Katherine D. Kavlock -S

for
Brent Showalter, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223362

Device Name
Cervical Spine Truss System – Stand Alone (CSTS-SA) Interbody Fusion Device

Indications for Use *(Describe)*
The Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels and is to be used with two titanium alloy screws or fixation anchors which accompany the device. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS-SA Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. When using the CTST-SA interbody with fixation anchors, the device must be used with supplemental fixation.

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.

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510(k) Summary

Date Prepared: February 2, 2023
Contact: Jessee Hunt, President
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Phone: (800) 285-7090
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade Name: Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: OVE
Panel Code: 87

Purpose:
The purpose of this submission is to update the Cervical Spine Truss System – Stand Alone (CSTS-SA) implant offering with the addition of fixation anchors.

Indications for Use:
The Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels and is to be used with two titanium alloy screws or fixation anchors which accompany the device. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS-SA Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. When using the CTST-SA interbody with fixation anchors, the device must be used with supplemental fixation.

Device Description:
The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone through growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface roughness. The implant is made from Ti6Al4V alloy. The device is available in a variety of sizes to accommodate the patient's

anatomy. Screws or fixation anchors are inserted through the anterior portion of the implant into adjacent vertebral bodies for bony fixation.

Predicate Device(s):
The primary predicate device is the 4WEB Medical Cervical Spine Truss System – Stand Alone (K190870). Additional predicates for this submission is the 4WEB Medical Cervical Spine Truss System (K173159) and the 4WEB Medical Lateral Spine Truss System – Plating Solution (K203065).

Performance Standards:
Performance testing has been completed on the CSTS-SA implants per the following standards:

- ASTM F2077 – Static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion testing
- ASTM F-04.25.02.02 - Expulsion testing
- ASTM F2267 – Subsidence testing

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

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