January 5, 2023

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

Re: K221266
Trade/Device Name: Cervical Spine Truss System (CSTS) Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 5, 2022
Received: December 7, 2022

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,

Brent Showalter -S

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)*
K221266

Device Name
Cervical Spine Truss System (CSTS) Interbody Fusion Device

Indications for Use *(Describe)*
The Cervical Spine Truss System (CSTS) 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS 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. The device must be used with supplement 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: April 18, 2022
Contact: Jessee Hunt, President
4WEB, Inc.
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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 (CSTS) Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: ODP
Panel Code: 87

Purpose:
The purpose of this submission is to update the system with design changes to the interbody devices.

Indications for Use:

The Cervical Spine Truss System (CSTS) 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS 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. The device must be used with supplement 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.

Predicate Device(s):
The primary predicate device is the 4WEB Cervical Spine Truss System (CSTS) Interbody Fusion Device (K173159). The reference predicate is the 4WEB Cervical Spine Truss System Stand Alone (CSTS-SA) Interbody Fusion Device (K190870).

Performance Standards:
Validated finite element analysis demonstrated that the product line extension for the Cervical Spine Truss System (CSTS) does not introduce a new worst-case compared to the previously cleared 4WEB Cervical Spine Truss System-Stand Alone (CSTS-SA) devices for mechanical performance of the device.

Performance testing has been completed per the following standards for the combined Cervical Spine Truss Systems (CSTS & CSTS-SA):

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic axial compression shear per ASTM F2077
- Static and dynamic torsion per ASTM F2077
- Subsidence Testing per ASTM F2267-04
- Expulsion testing
- MR image artifact per ASTM F2119
- RF 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 CSTS 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 regarding indications for use, materials, function, size, and simulated testing. These comparisons demonstrate substantial equivalence to the predicate devices.

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