May 18, 2022

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

Re: K212527
Trade/Device Name: Cervical Spine Truss System Plating Solution (CSTS-PS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ

Dear Richard Jansen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 17, 2022. Specifically, FDA is updating the device name in the Indications for Use as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Colin O'Neill, OHT6: Office of Orthopedic Devices, colin.oneill@fda.hhs.gov.

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 17, 2022

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

Re: K212527
Trade/Device Name: Cervical Spine Truss System Plating Solution (CSTS-PS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 14, 2022
Received: April 18, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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)*
K212527

Device Name
Cervical Spine Truss System Plating Solution (CSTS-PS)

Indications for Use *(Describe)*
The Cervical Spine Truss System Plating Solution (CSTS-PS) is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1.

The Cervical Spine Truss System Plating Solution (CSTS-PS) is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: April 12, 2022
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: Cervical Spine Truss System Plating Solution (CSTS-PS)
Product Class: Class II
Classification: 21 CFR §888.3060
Common Name: Spinal intervertebral body fixation orthosis
Product Codes: KWQ

Indications for Use:
The Cervical Spine Truss System Plating Solution (CSTS-PS) is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1.

The Cervical Spine Truss System Plating Solution (CSTS-PS) is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Device Description:
The Cervical Spine Truss System Plating Solution (CSTS-PS) is comprised of cervical plates and screws. The cervical plates have a rotating locking tab for each double screw position to prevent back-out of the screw. The plates are available in 1-level, 2-level, 3-level, 4-level, and 5-level configurations. Each plate is available in multiple lengths to accommodate varying patient anatomy. The screws are available in two diameters and various lengths. All CSTS-PS plates and screws are made from Ti6Al4V alloy.

Predicate Device(s):
The primary predicate device is the Nuvasive Archon Anterior Cervical Plate System (K131025). Additional predicates include the 4WEB Lumbar Spine Truss System Plating Solution (K203065), 4WEB Cervical Spine Truss System (K173159), and 4WEB Cervical Spine Truss System-Stand Alone (K190870).

Performance Standards:
4WEB has conducted static compression bending, dynamic compression bending, static torsion, and screw push out testing per ASTM F1717 and ASTM F543 on the subject device. All performance testing has met the acceptance criteria established in FDA Guidance Document, *Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway., December 11, 2020*. The CSTS-PS implants are MR Conditional per ASTM F2503.

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

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