4Web, Inc.
% Rich Jansen
Consultant
Silver Pine Consulting, LLC.
3851 Mossy Oak Drive
Ft. Myers, Florida 33905

March 10, 2021

Re: K203065
Trade/Device Name: Lumbar Spine Truss System Plating Solution (LSTS-PS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, OVD
Dated: February 6, 2021
Received: February 8, 2021

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. 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,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203065

Device Name
Lumbar Spine Truss System Plating Solution (LSTS-PS)

Indications for Use *(Describe)*
The Lumbar Spine Truss System Plating Solution (LSTS-PS) without integrated fixation is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The LSTS-PS is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The LSTS-PS with integrated fixation is intended to be attached and remain attached to the Lateral Spine Truss System (LSTS) Interbody Fusion Device after implantation. In this configuration the LSTS-PS must only be used to treat patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The 1-hole 4WEB LSTS-PS with integrated fixation is intended to be used with supplemental fixation (e.g. posterior 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 3, 2021
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: Lumbar Spine Truss System Plating Solution (LSTS-PS)
Product Class: Class II
Classification: 21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Common Name: Intervertebral Body Fusion Device with Integrated Fixation
Product Codes: KWQ, OVD
Panel Code: 87

Indications for Use:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) without integrated fixation is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The LSTS-PS is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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Device Description:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) is comprised of lumbar plates and screws. The lumbar plates have a rotating locking tab for each screw position to prevent back-out of the

screw. The plates are available in 1-hole, 2-hole, and 4-hole integrated configurations and 2-hole and 4-hole non-integrated configurations. Each plate is available in multiple lengths for single level fusion. The screws are available in two diameters and various lengths to accommodate the patient's anatomy. All LSTS-PS plates and screws are made from Ti6Al4V alloy.

Predicate Device(s):
The primary predicate device is the CoreLink Lateral Plate System (K190016). Reference predicates include the 4WEB Lateral Spine Truss System (K172392), 4WEB Anterior Spine Truss System – Stand Alone (K200002) and Nuvasive Modulus XLIF Interbody System (K192760).

Performance Standards:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) has been tested per the following:

- Static axial compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic axial compression bending fatigue per ASTM F1717
- Axial screw pushout per ASTM F543
- Static axial compression per ASTM F2077
- Static compression shear per ASTM F2077
- Dynamic axial compression fatigue per ASTM F2077
- Dynamic compression shear fatigue per ASTM F2077

The results of this non-clinical testing show that the strength of the LSTS-PS 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 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 LSTS-PS devices are substantially equivalent to the predicate devices and raise no new questions of safety or effectiveness.