February 12, 2026

4WEB, Inc.
Jarod Oldham
Vice President of R&D and Advanced Manufacturing
2801 Network Blvd.
Suite 620
Frisco, Texas 75034

Re: K253201
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
Dated: September 26, 2025
Received: January 20, 2026

Dear Jarod Oldham:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE SMITH -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253201

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

The Lumbar Spine Truss System Plating Solution (LSTS-PS) non-integrated plate 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, anterolateral, or anterior 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 integrated plate may be attached and remain attached to a Lateral Spine Truss System (LSTS) Interbody Fusion Device or an Anterior Spine Truss System (ASTS) 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 integrated plate is intended to be used with supplemental fixation (e.g. posterior fixation).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared: February 11, 2026
Contact: Jarod Oldham, Vice President of R&D and Advanced Mfg.
4WEB, Inc.
2801 Network Blvd., Suite 620
Frisco, TX 75034
Phone: (800) 285-7090
Fax: 972-488-1816

Trade Name: Lumbar Spine Truss System Plating Solution (LSTS-PS)
Product Class: Class II
Classification: 21 CFR §888.3060
Common Name: Spinal intervertebral body fixation orthosis.
Product Codes: KWQ
Panel Code: 87

Purpose: The purpose of this Special 510k submission is to expand the indications of the 4WEB Lumbar Spine Truss System Plating Solution (LSTS-PS) to allow use of the integrated LSTS-PS plates with 4WEB's Anterior Spine Truss System implants and to add smaller sizes of the 2-hole and 4-hole non-integrated plates and the 1-hole, 2-hole, and 4-hole integrated plates.

Predicate Device(s):
The primary predicate device is the 4WEB Lumbar Spine Truss System Plating Solution (LSTS-PS) (K203065). A reference predicate is the Zimmer Biomet (Lanx) Timberline MPF (Lanx Spinal Fixation System) (K131547).

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.

Indications for Use:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) non-integrated plate 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, anterolateral, or anterior 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 integrated plate is intended to be attached and remain attached to a Lateral Spine Truss System (LSTS) Interbody Fusion Device or the Anterior Spine Truss System (ASTS) 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 integrated plate is intended to be used with supplemental fixation (e.g. posterior fixation).

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.

Performance Standards:
The smaller sizes of the LSTS-PS (non-integrated and integrated) and use of the integrated LSTS-PS plates with the 4WEB Lateral Spine Truss System (LSTS) Interbody Fusion Device or the 4WEB Anterior Spine Truss System (ASTS) Interbody Fusion Device does not represent a new worst case. Previous testing on the primary predicate device (K203065) was completed to the following standards:

- 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 per ASTM F2077
- Dynamic compression shear per ASTM F2077

Additional testing was conducted with the 4WEB LSTS-PS plates and the 4WEB Anterior Spine Truss System Interbody Fusion Device to the following standards:

- Dynamic compression shear 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.

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.