April 22, 2024

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

Re: K233966
Trade/Device Name: Anterior Spine Truss System-Stand Alone (ASTS-SA)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 25, 2024
Received: March 27, 2024

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

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)*
K233966

Device Name
Anterior Spine Truss System – Stand Alone (ASTS-SA)

Indications for Use *(Describe)*
The Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device is a stand-alone interbody fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbosacral spine at one or two contiguous disc levels. Each interbody fusion device is intended to be used with three titanium alloy screws or anchors which accompany the implant. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g. posterior fixation). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. ASTS-SA Interbody Fusion Devices are used as an adjunct to fusion in the lumbosacral spine and are placed via an anterior approach at the L2 to S1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). When using the ASTS-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.

510(k) Summary

Date Prepared: February 2, 2024
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: 4WEB Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device with Integrated Fixation
Product Codes: OVD
Panel Code: 87

Purpose:
The purpose of this submission is to update the Anterior Spine Truss System – Stand Alone (ASTS-SA) implant offering.

Indications for Use:
The Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device is a stand-alone interbody fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbosacral spine at one or two contiguous disc levels. Each interbody fusion device is intended to be used with three titanium alloy screws or anchors which accompany the implant. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g. posterior fixation). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. ASTS-SA Interbody Fusion Devices are used as an adjunct to fusion in the lumbosacral spine and are placed via an anterior approach at the L2 to S1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). When using the ASTS-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 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 Anterior Spine Truss System – Stand Alone (K200002). An additional predicate is the 4WEB Medical Cervical Spine Truss System – Stand Alone (K223362). A reference predicate is the 4WEB Medical Lateral Spine Truss System Plating Solution (K203065).

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

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

Performance testing on the subject device has been completed per the following standards:

- ASTM F2077 – Dynamic axial compression and dynamic compression-shear testing.
- Expulsion Testing

MR Conditional Testing has been submitted with the primary predicate device, the 4WEB Anterior Spine Truss System – Stand Alone (K200002) and the reference predicate device, the Lateral Spine Truss System Plating Solution (K203065) to the following standards:

- MR image artifact per ASTM F2119
- MR induced heating per ASTM F2182
- MR induced torque per ASTM F2213
- MR induced displacement force per ASTM F2052

Technological Characteristics:
4WEB, Inc. has compared these devices to the previously cleared predicate devices in regards 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 ASTS-SA devices are substantially equivalent to the predicate devices and raise no new questions of safety or effectiveness.