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

Re: K170851  
Trade/Device Name: Anterior Spine Truss System (STS) Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: July 6, 2017  
Received: July 10, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address [http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm). 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 [http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address [http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Anterior Spine Truss System (STS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
510(k) Summary

Date Prepared: August 7, 2017

Contact: Jesse Hunt, President
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Regulatory Contact: Rich Jansen, Pharm. D.
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Trade Name: Anterior Spine Truss System (STS) Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: MAX
Panel Code: 87

Purpose:
The purpose of this submission is to update the system with design changes to implants and instruments, update sterile packaging, add new EBM machining, revise the Indications for Use, and add MR Conditional labeling.

Indications for Use:
The Anterior Spine Truss System (STS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Device Description:
The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone 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 and lordotic angles to accommodate the patient’s anatomy.

**Predicate Device(s):**

The primary predicate device is the 4WEB ALIF STS (K112316). Additional predicates include K142112, K150135 and K160924.

**Performance Standards:**

Performance testing has been completed per the following standards:
- ASTM F2077 – Static and dynamic axial compression, static and dynamic compression shear, and static torsion
- ASTM F2267-04 – Subsidence Testing
- ASTM F2119 – MR Image Artifact
- ASTM F2052 – MR Induced Displacement Force
- ASTM F2213 – MR Induced Torque
- ASTM F2182 – MR Induces Heating
- Expulsion testing per accepted industry standard.

**Technological Characteristics:**

4Web, Inc. has compared these changes to the previously cleared predicate devices in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

**Conclusion:**

4WEB, Inc. concludes that the Anterior Spine Truss System (STS) devices are substantially equivalent to the predicate devices.