



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 6, 2016

4WEB, Incorporated
% Rich Jansen, Ph.D.
Consultant
Silver Pine Consulting, LLC.
11821 Bramble Cove Drive
Ft. Myers, Florida 33905

Re: K153436

Trade/Device Name: LATERAL Spine Truss System
Regulation Number: 21 CFR 888.3080
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MAX
Dated: May 9, 2016
Received: May 10, 2016

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

Sincerely yours,

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

510(k) Number (if known)
K153436

K153436
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Device Name
LATERAL Spine Truss System

Indications for Use (Describe)

The Lateral Spine Truss System (STS) is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. 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 bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

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: June 2, 2016

Contact: Jessee Hunt, President
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade Name: LATERAL Spine Truss System
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: MAX
Panel Code: 87

Indications for Use:

The Lateral Spine Truss System (STS) is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. 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 bone. 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 device is available in a variety of sizes to accommodate the patient's anatomy. The implant is made from Ti6Al4V alloy (ASTM F-1108).

Predicate Device(s):

The 4WEB LATERAL STS is substantially equivalent to the primary predicate, the 4WEB ALIF STS (K112316). Additional predicated devices are the 4WEB PSTS (K143258), 4WEB ALIF STS (K083894), and Medtronic Clydesdale Spinal System (K132897).

Performance Standards:

Validated FEA, comparing the subject device to PLIF STS (K143258), was conducted to evaluate the mechanical performance of the devices under different loading scenarios, including pure

compression and combined compression and shear. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology.

Technological Characteristics:

4Web, Inc. has compared the Lateral STS to the 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 these LATERAL STS devices are substantially equivalent to the predicate devices and raise no new questions of safety or effectiveness.