



4Web, Inc.
% Rich Jansen
Consultant
Silver Pine Consulting
11821 Bramble Cove Drive
Ft. Myers, Florida 33905

January 8, 2018

Re: K173159

Trade/Device Name: Cervical Spinal Truss System (CSTS) Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 13, 2017
Received: December 14, 2017

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. 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.

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> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Katherine D. Kavlock -S

for
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)

K173159

Device Name

Cervical Spine Truss System (CSTS) Interbody Fusion Device

Indications for Use (Describe)

The Cervical Spine Truss System (CSTS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device must be used with supplement 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: January 5, 2018

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: Cervical Spine Truss System (CSTS) Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: ODP
Panel Code: 87

Purpose:

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

Indications for Use:

The Cervical Spine Truss System (CSTS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device must be used with supplement 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.

Predicate Device(s):

The primary predicate device is the 4WEB CSTS (K121741). Additional predicates include K142112, K171496 and K111119.

Performance Standards:

Performance testing has been completed per the following standards:

ASTMF2077 - Static and dynamic axial compression, static and dynamic compression shear, and static and dynamic 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 CSTS devices are substantially equivalent to the predicate devices.