SPINE WAVE

SEP - 8 2009

510(k) Summary
StaXx® XD System

Submitter Information

Spine Wave, Inc.
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Contact: Roaida Rizkallah
Date Prepared: August 26, 2009

Device Information

Trade name:	StaXx® XD System
Common name:	Vertebral Body Replacement
Classification:	Class II per 21 CFR 888.3070
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Product Code:	MQP

Device Description

The StaXx® XD System is a vertebral body replacement device composed of wafers that are stacked into an expandable implant to adjust its height. The implant components are manufactured from PEEK-OPTIMA with 6% Barium Sulfate. The system also includes a delivery device to implant and expand the implant. The device is offered in sizes ranging from 7mm to 30mm.

Intended Use

The StaXx® XD System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be placed bilaterally and used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

Substantial equivalence

The StaXx® XD System described in this submission is substantially equivalent to the following device:

Predicate Device	Manufacturer	510(k) No.
StaXx® XD System	Spine Wave, Inc.	K052670

In addition, mechanical testing demonstrated that the StaXx® XD System is equivalent to its predicate device. The minor differences between the StaXx® XD System and the predicate device do not raise any new questions of safety or effectiveness. Thus, the StaXx® XD System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Spine Wave, Inc.
% Ms. Roaida Rizkallah
Senior Regulatory Affairs Specialist
2 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

SEP - 3 2009

Re: K090315
Trade/Device Name: StaXx® XD System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 26, 2009
Received: August 31, 2009

Dear Ms. Rizkallah:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K090315

Device Name: StaXx® XD System

Indications for Use:

The StaXx® XD System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be placed bilaterally and used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kareem S. Bruny for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090315