SPINEWAVE

510(k) Summary
StaXx™ XD System

APR 27 2006

I. Submitter Information

Spine Wave, Inc.
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Contact: Ronald K. Smith
Date Prepared: March 5, 2006

II. Device Information

Trade name: StaXx™ XD System
Common name: Vertebral Body Replacement
Classification: Class II per 21 CFR 888.3060
Classification Name: Spinal Intervertebral Fixation Orthosis
Product Code: MQP

III. Device Information

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 system. The device is offered in sizes ranging from 7mm to 30mm.

IV. 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 bone graft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx™ XD System is the Stryker Xia® Spinal System.

V. Substantial equivalence

The StaXx™ XD System was demonstrated to be substantially equivalent to the VERTE-STACK™ Spinal System (Medtronic Sofamor Danek, K043566), the Blackstone™ PEEK VBR System (Blackstone Medical, Inc., K041939 and K033702), the PEEK Tetris™ System (SIGNUS Medical LLC, K031757), the Sustain Radiolucent Spacer (Globus Medical Inc., K040284) and The Wafer System (Spine Wave, K033303). In addition, mechanical testing demonstrated

that the StaXx™ XD System meets the performance requirements for its intended use. Any differences between the StaXx™ XD System and the predicate devices do not affect the safety or effectiveness of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Spine Wave, Inc.
c/o Mr. Ronald K. Smith
Director, Quality and Regulatory Affairs
Two Enterprise Drive, Suite 302
Shelton, Connecticut 06484

Re: K052670
Trade/Device Name: StaXx™ XD System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 26, 2006
Received: January 27, 2006

Dear Mr. Smith:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indications for Use

510(k) Number (if known): K052670

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 bone graft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx™ XD System is the Stryker Xia® Spinal 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052670