SPINEWAVE

APR 1 1 2013

510(k) Summary
StaXx® IB System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1839
Telefax: 203-944-9493

Contact: Roaida Rizkallah
Date Prepared: April 11, 2013

2. Device Information

Trade Name: StaXx® IB System
Common Name: Intervertebral Body Fusion Device
Classification: Class II (special controls) per 21 CFR 888.3080
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
Product Code: MAX

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new intervertebral body fusion device.

4. Predicate Device Information

The StaXx® IB System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
Distractable Wave Cage	Advanced Medical Technologies	K083626
Caliber™ Spacer	Globus Medical, Inc.	K102293
Opticage™ Interbody Fusion Device	Interventional Spine, Inc.	K113527

5. Device Description

The StaXx® IB System is an intervertebral body fusion device composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implants are to be used with autogenous bone graft material. The implant components are manufactured from both PEEK-OPTIMA and PEEK-OPTIMA with 6% Barium Sulfate. The system also includes a delivery device to both implant and expand the system.

6. Intended Use

The StaXx® IB System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The StaXx® IB System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

7. Comparison of Technological Characteristics

The substantial equivalence of the StaXx® IB System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

The following mechanical tests were performed to demonstrate the substantial equivalence of the StaXx® IB System to its predicate:

- Static and dynamic axial compression (per ASTM F2077)
- Static and dynamic compression shear (per ASTM F2077)
- Subsidence (per ASTM F2267)

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the StaXx® IB System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Spine Wave, Incorporated
% Ms. Roaida Rizkallah
Regulatory Affairs Manager
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Letter dated: April 11, 2013

Re: K123461
Trade/Device Name: StaXx® IB System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 13, 2013
Received: March 14, 2013

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. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

A. Indications for Use

510(k) Number (if known): K123461

Device Name: StaXx® IB System

Indications for Use:

The StaXx® IB System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The StaXx® IB System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

Prescription Use X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices