



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

February 19, 2015

Spine Wave, Incorporated
Ms. Roaida Johnson
Senior Regulatory Affairs Manager
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K142996

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 20, 2015
Received: January 21, 2014

Dear Ms. Johnson:

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 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,

Lori A. Wiggins -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)

K142996

K142996

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Device Name

StaXx® XD System

Indications for Use (Describe)

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.

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 StaXx[®] XD System

1. Submitter Information

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

Contact: Roaida R. Johnson
Date Prepared: October 15, 2014

2. Device Information

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

3. Purpose of Submission

The purpose of this submission is to gain clearance to add a commercially pure titanium coating to the StaXx[®] XD System.

4. Predicate Device Information

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

	Device	Manufacturer	510(k) No.
Primary Predicate	StaXx [®] XD System	Spine Wave, Inc.	K133207
Additional Predicate	Calix [™] PC Spinal Implant System	X-Spine	K112036

5. Device Description

The StaXx[®] XD System is composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implants are to be used with autograft or allograft and supplemental spinal fixation. The implants are manufactured from PEEK-OPTIMA with 6% Barium Sulfate, tantalum markers (ASTM F560), and a plasma-sprayed commercially pure titanium coating (ASTM F1580). The implants are available in a variety of shapes and sizes, to accommodate variations in anatomy. The system also includes a delivery device to both implant and expand the implant.

6. 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.

7. Comparison of Technological Characteristics

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

8. Non-Clinical Performance Testing

The following tests were performed for characterization of the commercially pure titanium coating:

- Coating Microstructure (ASTM F1854)
- Shear Fatigue Testing (ASTM F1160)
- Static Shear Testing (ASTM F1044)
- Tensile Testing (ASTM F1147)
- Abrasion Testing (ASTM F1978)

The following tests were performed to demonstrate the substantial equivalence of the StaXx[®] XD System to its predicate:

- Static and dynamic axial compression (ASTM F2077)
- Dynamic torsion (ASTM F2077)
- Wear debris analysis (ASTM F1877)
- Expulsion

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the StaXx[®] XD 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.