



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Spine Wave, Incorporated  
Ms. Gail Yaeker-Daunis  
Senior Regulatory Affairs Specialist  
3 Enterprise Drive, Suite 210  
Shelton, Connecticut 06484

January 15, 2016

Re: K152620

Trade/Device Name: Spine Wave Gen II Expandable Interbody System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: December 16, 2015  
Received: December 17, 2015

Dear Ms. Yaeker-Daunis:

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 Parts 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,

**Mark N. Melkerson -S**

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)

K152620

### Spine Wave Gen II Expandable Interbody System

Indications for Use (Describe)

The Spine Wave Gen II Expandable Interbody 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 when implanted using a posterior surgical approach and levels L2-L5 when implanted using a lateral surgical approach. 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 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.

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**

### **Spine Wave Gen II Expandable Interbody System**

#### **1. Submitter Information**

*Submitter:* Spine Wave, Inc.  
*Address:* Three Enterprise Drive  
Suite 210  
Shelton, CT 06484  
*Telephone:* 203-712-1894  
*Telefax:* 203-944-9493

*Contact:* Gail Yaeker-Daunis  
*Date Prepared:* January 14, 2016

#### **2. Device Information**

*Trade Name:* Spine Wave Gen II Expandable Interbody 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 Spine Wave Gen II Expandable Interbody System described in this submission is substantially equivalent to the following predicates:

	<b><u>Device</u></b>	<b><u>Manufacturer</u></b>	<b><u>510(k) No.</u></b>
<b>Primary Predicate</b>	StaXx <sup>®</sup> IBL System	Spine Wave, Inc.	K131071
Additional Predicate	StaXx <sup>®</sup> IBL System	Spine Wave, Inc.	K132719
Additional Predicate	StaXx <sup>®</sup> IB	Spine Wave, Inc.	K123461
Additional Predicate	Caliber <sup>®</sup> / Caliber L <sup>®</sup> Spacer	Globus Medical Inc.	K123231
Additional Predicate	Patriot <sup>®</sup> Spacer	Globus Medical Inc.	K122097
Additional Predicate	LDR Spine USA Avenue <sup>®</sup> L Interbody Fusion System	LDR Spine USA	K113285
Additional Predicate	Pezo <sup>™</sup> PEEK Cage Family	Ulrich GmbH & Co. KG	K103814
Additional Predicate	Abacus <sup>®</sup> Spacer System	Spine Wave, Inc.	K140007
Additional Predicate	Biomet Fusion System	Biomet Spine	K141791
Additional Predicate	Synfix-LR SPACER	Synthes Spine Co. LP	K072253

## 5. Device Description

The Gen II Expandable Interbody System is composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implants are manufactured of titanium alloy (Ti-6Al-4V, ASTM F136), PEEK-OPTIMA with 6% BaSO<sub>4</sub>, and commercially pure titanium (ASTM F1580). The Spine Wave Gen II Expandable Interbody System Implants are provided in various configurations to address the anatomical needs of a variety of patients and to accommodate various surgical approaches to the lumbar spine. The implants are to be used with autogenous bone graft material and supplemental fixation. The System also includes a delivery device that is used to both place and expand the implant. The implants are provided sterile.

## 6. Indications for Use

The Spine Wave Gen II Expandable Interbody 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 when implanted using a posterior surgical approach and levels L2-L5 when implanted using a lateral surgical approach. 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 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 Spine Wave Gen II Expandable Interbody System to predicates is shown by similarity in intended use, indications for use, materials and performance.

## **8. Non-Clinical Performance Data**

The following tests have been performed for characterization of the commercially pure titanium coating to demonstrate substantial equivalence of the system to its predicate:

- Coating Microstructure (ASTM F1854)
- Shear Testing of Calcium Phosphate Coatings and Metallic Coatings (ASTM F1044)
- Shear Fatigue Testing (ASTM F1160)
- Tensile Testing (ASTM F1147)
- Abrasion Testing (ASTM F1978)

The following mechanical tests were performed to demonstrate the substantial equivalence of the system to its predicates:

- Static and dynamic axial compression (per ASTM F2077)
- Static and dynamic compression shear (per ASTM F2077)
- Subsidence (per ASTM F2267)
- Wear Debris Analysis (per ASTM F1877)

## **9. Conclusion**

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Spine Wave Gen II Expandable Interbody System has been shown to be substantially equivalent to the predicate devices identified in this submission.