DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 9, 2015

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

Re: K151581
Trade/Device Name: Leva™ Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 9, 2015
Received: June 11, 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151581

Device Name
Leva™ Spacer System

Indications for Use *(Describe)*

The Leva™ Spacer 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 Leva™ Spacer 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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SPINE WAVE

510(k) Summary
Leva™ Spacer 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:	Gail Yaeker-Daunis
Date Prepared:	June 9, 2015

2. Device Information

Trade Name:	Leva™ Spacer 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 line addition to the Leva™ Spacer System, to add additional implant sizes and associated instruments.

4. Predicate Device Information

The Leva™ Spacer System described in this submission is substantially equivalent to the following predicates:

Primary Predicate Device	**Manufacturer**	**510(k) No.**
Leva™ Spacer System	Spine Wave, Inc.	K141980 and K150285

5. Device Description

The Leva™ Spacer System is a lumbar intervertebral body fusion device fabricated from unalloyed commercially pure (Class II) titanium per ASTM F67. The device is available in both expandable and fixed configurations. The expandable device is provided in a collapsed form and is expanded to a predefined height in-situ using the Leva™ Inserter Instrument. Both the fixed and expandable implants are provided in different heights to

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accommodate the anatomical needs for a range of patients. The implants are designed to accommodate autogenous bone graft material. The implants have curved endplates to conform to the bony endplates of the patient and ridges on the endplates to resist expulsion.

6. Indications for Use

The Leva™ Spacer 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 Leva™ Spacer 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 Leva™ Spacer System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

The modified implants were compared to constructs previously tested in static and dynamic axial compression (ASTM F2077), static and dynamic compression shear (ASTM F2077), and subsidence (ASTM F2267). Finite Element Analysis and mechanical testing which included oblique compressive shear (ASTM F2077) and subsidence (ASTM F2267) demonstrated substantial equivalence to the predicate devices.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Leva™ Spacer 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.