



Food and Drug Administration
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Silver Spring, MD 20993-0002

Spine Wave, Inc.
Amy Noccioli
Regulatory Affairs Specialist
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

April 6, 2017

Re: K163246

Trade/Device Name: Leva® Anterior Expandable Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 2, 2017
Received: March 3, 2017

Dear Ms. Noccioli:

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" (21 CFR 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,

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)

K163246

Device Name

Leva® Anterior Expandable Spacer System

Indications for Use (Describe)

The Leva® Anterior Expandable 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® Anterior Expandable 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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510(k) Summary

Leva[®] Anterior Expandable Spacer System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
 Suite 210
 Shelton, CT 06484
Telephone: 203-712-1842
Telefax: 203-944-9493

Contact: Amy Noccioli
Date Prepared: November 16, 2016

2. Device Information

Trade Name: Leva[®] Anterior Expandable 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 new intervertebral body fusion device.

4. Predicate Device Information

The Leva[®] Anterior Expandable 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

Reference Predicate Devices	Manufacturer	510(k) No.
MAGNIFY [™] Spacer	Globus Medical, Inc.	K142498
PATRIOT [®] Spacer	Globus Medical, Inc.	K072970

5. Device Description

The Leva[®] Anterior Expandable Spacer is an expandable lumbar intervertebral body fusion device manufactured from unalloyed commercially pure titanium per ASTM F67. The Leva[®] Anterior Expandable Insertor, a reusable surgical instrument, expands the spacer (which is provided in a collapsed form) *in situ* to a predefined height. To accommodate the anatomical needs of a variety of patients, the spacer is available in a range of sizes. The superior and inferior surfaces of the spacer are convex with a lordotic angle to conform to the vertebral endplates, and ridges on both surfaces help resist expulsion. The spacer is designed to accommodate autogenous bone graft material.

6. Indications for Use

The Leva[®] Anterior Expandable 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[®] Anterior Expandable 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 Leva[®] Anterior Expandable Spacer System has technological characteristics similar to the predicate devices, including intended use, performance, design, material composition, and range of sizes.

8. Performance Data

Spine Wave performed the following testing to demonstrate that the Leva[®] Anterior Expandable Spacer System is substantially equivalent to its predicate:

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

9. Conclusion

The indications for use, technological characteristics, performance testing, and comparison to the predicates show that the Leva[®] Anterior Expandable Spacer System is substantially equivalent to the predicate devices identified in this submission and does not present any new issues of safety or effectiveness.