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

November 22, 2016

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

Re: K161993
Trade/Device Name: Leva® Anterior Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 27, 2016
Received: October 28, 2016

Dear Sanja Jahr:

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,

Vincent J. Devlin -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)*

K161993

Device Name
Leva® Anterior Interbody System

Indications for Use *(Describe)*

The Leva® Anterior Interbody System is a stand-alone system 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 Interbody System is intended to be filled with autogenous bone graft material and used with the bone screws provided. 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 Interbody System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1870
Telefax: 203-944-9493

Contact: Sanja Jahr
Date Prepared: October 27, 2016

2. Device Information

Trade Name: Leva® Anterior Interbody System
Common Name: Intervertebral Body Fusion Device
Classification: Class II (special controls) per 21 CFR 888.3080
Classification Name: Intervertebral Fusion Device with Integrated Fixation, Lumbar
Product Code: OVD

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 Interbody System described in this submission is substantially equivalent to the following predicates:

Primary Predicate Device	Manufacturer	510(k) No.
Zuma System	SeaSpine	K082926

Reference Predicate Devices	Manufacturer	510(k) No.
Vault ALIF System	Precision Spine	K130445
VisuALIF	SpineSmith	K122168
Independence	Globus	K120101
Irix-A	X-Spine	K133947
Chesapeake Stabilization System	K2M	K142487
The STALIF TT™	Surgicraft Spine	K073109

5. Device Description

The Leva® Anterior Interbody System is family of stand-alone lumbar intervertebral body fusion devices fabricated from Ti-6Al-4V per ASTM F1472 and Ti-6Al-4V ELI per ASTM F136. The device includes integrated plate/screw fixation available in two configurations. In both device configurations, the surgeon inserts the bone screws through the anterior plate screw holes to provide fixation to the vertebral bodies. The device is intended to be filled with autogenous bone graft material. Both implant configurations are provided in various dimensions to accommodate the anatomical needs for a range of patients. The implants have convex endplates to conform to the bony endplates of the patient and ridges on the endplates to resist expulsion.

6. Indications for Use

The Leva® Anterior Interbody System is a stand-alone system 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 Interbody System is intended to be filled with autogenous bone graft material and used with the bone screws provided. 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 Interbody System has the same technological characteristics as 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 the Leva® Anterior Interbody System is substantially equivalent to its predicate:

- Static and dynamic axial compression (per ASTM F2077)
- Static and dynamic compression shear (per ASTM F2077)
- Static push-out (per ASTM Draft F-04.25.02.02)
- Subsidence (per ASTM F2267)

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Leva® Anterior Interbody 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.