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

Spine Wave, Inc.
Amnon Talmor
Senior Regulatory Affairs Manager
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

February 16, 2017

Re: K162760
Trade/Device Name: Spine Wave Anterior Cervical Spine System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: January 9, 2017
Received: January 10, 2017

Dear Mr. Talmor:

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

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)*

K162760

Device Name

Spine Wave Anterior Cervical Spine System

Indications for Use *(Describe)*

The Spine Wave Anterior Cervical Spine System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) weeks of non-operative treatment. The Spine Wave Anterior Cervical Spine System is to be used with autogenous bone graft and placed via an open, anterior approach; supplemental fixation (i.e., posterior cervical screw fixation) is required to properly utilize this 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
Spine Wave Anterior Cervical Spine System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484

Contact: Amnon Talmor
Date Prepared: February 15, 2017

2. Device Information

Trade Name: Spine Wave Anterior Cervical Spine System
Common Name: Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification: Class II (special controls) per 21 CFR 888.3080
Classification Name: Intervertebral Body Fusion Device
Product Code: OVE

3. Predicate Device Information

The Spine Wave Anterior Cervical Spine System described in this submission is substantially equivalent to the following:

Primary Predicate Device	**Manufacturer**	**510(k) No.**
ROI-C Cervical Cage System	LDR Spine USA	K150765

Additional Predicate Devices	**Manufacturer**	**510(k) No.**
Cervical Interbody Spacer System	Choice Spine	K091531
Gen II Expandable Interbody System	Spine Wave	K152620
Leva® Interbody Device	Spine Wave	K153222
CapSure® PS Spine System	Spine Wave	K081228

4. Device Description

The Spine Wave Anterior Cervical Spine (ACS) System consists of a selection of non-sterile, single use cervical interbody cages indicated for skeletally mature

patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1.

The Spine Wave ACS cages are multi-component devices comprised of a cage body, anchor plate and graft cap. Spine Wave supplies the cage body and anchor plate as a paired combination, and the surgeon assembles the graft cap *in situ*. The Spine Wave ACS cages are offered in a variety of sizes and shapes to accommodate different patient anatomies and manufactured from titanium alloy (Ti-6Al-4V per ASTM F136), commercially pure titanium (ASTM F67) and PEEK-OPTIMA with 6% $BaSO_4$.

Using the Spine Wave ACS Inserter, the surgeon places the cage body with undeployed anchor plate into the disc space. After placement, the surgeon uses the cage inserter to deploy the superior and inferior portions of the anchor plate into the adjacent vertebral bodies and pack the open end of the cage with autograft. Once grafting is complete, the surgeon snaps the graft cap into the open end of the cage.

5. Indications for Use

The Spine Wave Anterior Cervical Spine System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disk level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) weeks of non-operative treatment. The Spine Wave Anterior Cervical Spine System is to be used with autogenous bone graft and placed via an open, anterior approach; supplemental fixation (i.e., posterior cervical screw fixation) is required to properly utilize this system.

6. Comparison of Technological Characteristics

The substantial equivalence of the Spine Wave Anterior Cervical Fusion Cage System to the listed predicate is shown by similarity in intended use, indications for use, materials and performance.

7. Non-Clinical Performance Data

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)
- Static and dynamic torsion
- Subsidence (per ASTM F2267)
- Static expulsion (per ASTM Draft Standard F-04.25.02.02)
- Simulated use testing

8. Conclusion

Based on the indications for use, technical characteristics, performance testing, and comparison to the predicates, the Spine Wave Anterior Cervical Spine System is substantially equivalent to the predicate devices identified in this submission and does not present any new issues of safety or effectiveness.