July 25, 2023

Spine Wave, Inc.
Ronald K. Smith
Executive VP, Quality, Regulatory & Clinical Affairs
3 Enterprise Drive
Shelton, Connecticut 06484

Re: K231275
Trade/Device Name: Exceed™ Biplanar Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 2, 2023
Received: May 2, 2023

Dear Mr. Smith:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231275

Device Name

Exceed™ Biplanar Expandable Interbody System

Indications for Use *(Describe)*

The Exceed™ Biplanar 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. 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 Exceed™ Biplanar Expandable Interbody System is to be used with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. The Exceed™ Biplanar Expandable Interbody System is to be used 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.

SPINE WAVE

510(k) Summary
Exceed™ Biplanar Expandable Interbody System

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
Telephone:	203-712-1846
Contact:	Ronald K. Smith
Date Prepared:	May 2, 2023

2. Device Information

Trade Name:	Exceed™ Biplanar Expandable Interbody System
Common Name:	Intervertebral Body Fusion Device
Classification:	Class II 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 Exceed™ Biplanar Expandable Interbody 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.	K153222

Additional Predicate Device	**Manufacturer**	**510(k) No.**
DualX® Expanding Titanium Posterior Lumbar Interbody Fusion System	Amplify Surgical, Inc.	K222203

5. Device Description

The Exceed™ Biplanar Expandable Interbody System is a lumbar intervertebral body fusion device fabricated from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The implant is provided unexpanded with a nose tapered in both the lateral and vertical planes, and is expanded *in situ* using the Exceed™ Inserter. The implant has a microscopic roughened surface with micro and nano-scale features on the superior and inferior surfaces for resistance to migration and to facilitate fusion. The implant is provided in different heights, lengths, and lordotic angles to accommodate the anatomical needs for a range of patients, and is designed to accommodate autogenous and/or allogenic bone graft material.

6. Indications for Use

The Exceed™ Biplanar 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. 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 Exceed™ Biplanar Expandable Interbody System is to be used with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. The Exceed™ Biplanar Expandable Interbody System is to be used 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 Exceed™ Biplanar Expandable Interbody System to the predicate is shown by similarity in intended use, indications for use, materials, and performance.

8. Performance Data

Nonclinical testing was performed on the Exceed™ Biplanar Expandable Interbody System to support substantial equivalence to the predicate device. The following testing was performed:

- Static and dynamic axial compression testing per ASTM F2077
- Static and dynamic compression shear testing per ASTM F2077
- Subsidence testing per ASTM F2267
- Particulate and wear analysis per ASTM F1877

9. Conclusion

The indications for use, technological characteristics, and performance testing show that the Exceed™ Biplanar Expandable Interbody System is substantially equivalent to the predicate device and does not present any new issues of safety or effectiveness.