August 29, 2022

Spine Wave, Inc.
Ronald Smith
Executive Vice President - Quality, Regulatory & Clinical Affairs
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K222362
Trade/Device Name: Salvo® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 3, 2022
Received: August 4, 2022

Dear Ronald 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,

for

Colin O'Neill, M.B.E.
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)*
K222362

Device Name
Salvo® Spine System

Indications for Use *(Describe)*
The Salvo® Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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
Salvo® Spine System

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
Telephone:	203-712-1846
Telefax:	203-944-9493
Contact:	Ronald K. Smith

Date Prepared:	August 3, 2022

2. Device Information

Trade Name:	Salvo® Spine System
Common Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR 888.3070
Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification Code:	NKB

3. Purpose of Submission

The purpose of this submission is to gain clearance for additional connectors to the Salvo® Spine System.

4. Predicate Device Information

The Salvo® Spine System described in this submission is substantially equivalent to the following predicate:

Primary Predicate Device	Manufacturer	510(k) No.
Salvo® Spine System	Spine Wave, Inc.	K202476

5. Device Description

The Salvo® Spine System is a thoracolumbosacral pedicle screw system designed to be implanted through a posterior surgical approach. The implants are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136, commercially pure titanium per ASTM F67, cobalt-chromium alloy per ASTM F1537 and PEEK-OPTIMA. The Salvo® Spine System consists of a variety of screws, rods, and connectors that create a rigid construct as an adjunct to fusion for internal fixation and stabilization of the thoracic, lumbar, and sacral spine.

6. Indications for Use

The Salvo® Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

7. Comparison of Technological Characteristics

The subject Salvo® Spine System has technological characteristics similar to the predicate device, including intended use and indications for use, performance, design, and material composition.

8. Performance Data

The Salvo® Spine System demonstrated substantially equivalent mechanical performance to the predicate device through dynamic compression bending mechanical testing with reference to ASTM F1717 and a risk analysis compared to the predicate device.

9. Conclusion

The indications for use, technological characteristics, and performance data show that the subject Salvo® Spine System is substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.