June 15, 2026

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

Re: K260286
Trade/Device Name: Dynamo™ Spinal Cement; Salvo® Spine System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB
Dated: May 20, 2026
Received: May 20, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL -S 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K260286 |

Please provide the device trade name(s).

Dynamo™ Spinal Cement;
Salvo® Spine System

Please provide your Indications for Use below.

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).

When used in a percutaneous approach with minimally invasive surgery (MIS) instrumentation, 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).

When the Salvo® Spine System fenestrated screws are used in conjunction with Dynamo™ Spinal Cements (MV or HV), the Salvo® Spine System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Salvo® fenestrated screws augmented with the Dynamo™ Spinal Cements (MV or HV) are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Dynamo™ Spinal Cements (MV or HV), when used in conjunction with the Salvo® Spine System fenestrated screws, are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine, in whom life expectancy is of insufficient duration to allow for achievement of fusion. Dynamo™ Spinal Cements (MV or HV) are limited for use at spinal levels where the structural integrity of the spine is not severely compromised.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

# 510(k) Summary

## 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 20, 2026

## 2. Device Information

*Device Trade Name:* Dynamo™ Spinal Cement; Salvo® Spine System
*Common Name:* Bone Cement (Posterior Screw Augmentation), Thoracolumbosacral Pedicle Screw System
*Classification Name:* Polymethylmethacrylate (PMMA) bone cement, Thoracolumbosacral Pedicle Screw System
*Device Class:* Class II
*Regulation Number:* 21 CFR § 888.3027, 21 CFR § 888.3070
*Product Code(s):* PML, NKB

## 3. Legally Marketed Predicate Devices

| Primary Predicate Device | | | |
|---|---|---|---|
| **510(k)** | **Trade Name** | **Manufacturer** | **Product Code** |
| K241034 | Meta+ Bone Cement & M.U.S.T. Fenestrated Pedicle Screw System | Medacta | PML, NKB |

| Additional Predicate Device | | | |
|---|---|---|---|
| **510(k)** | **Trade Name** | **Manufacturer** | **Product Code** |
| K240685 | Salvo® Spine System | Spine Wave | NKB |

## 4. Device Description Summary

The Salvo® Spine System is a non-cervical fixation device consisting of a selection of non-sterile, single-use screws, rods, and connectors that are assembled to create a rigid spinal construct. The implant components of this system are manufactured from titanium (ASTM F67), titanium alloy (ASTM F136), cobalt-chromium alloy (ASTM F1537), and PEEK-OPTIMA (LT3 (ASTM F2026) or LT1 with 6% barium sulfate).

Dynamo™ Spinal Cement is a self-hardening and ready to use polymethylmethacrylate (PMMA) bone cement with a high amount of radiopaque agent. Each unit contains two sterile components: the polymer (powder) and the liquid monomer. The liquid in the ampoule is sterilized by ultra-filtration, and the ampoule blister is sterilized using ethylene oxide. The powder is packaged in a double pouch and sterilized by gamma rays. The whole is packaged in a box.

The purpose of this submission is to gain clearance for Dynamo™ Spinal Cement to be used in conjunction with the Salvo® Spine System and to add new fenestrated bone screws to the Salvo® Spine System.

**5. Indications for Use**

Salvo® Spine System

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).

When used in a percutaneous approach with minimally invasive surgery (MIS) instrumentation, 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).

When the Salvo® Spine System fenestrated screws are used in conjunction with Dynamo™ Spinal Cements (MV or HV), the Salvo® Spine System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Salvo® fenestrated screws augmented with the Dynamo™ Spinal Cements (MV or HV) are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Dynamo™ Spinal Cement

Dynamo™ Spinal Cements (MV or HV), when used in conjunction with the Salvo® Spine System fenestrated screws, are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine, in whom life expectancy is of insufficient duration to allow for achievement of fusion. Dynamo™ Spinal Cements MV or HV) are limited for use at spinal levels where the structural integrity of the spine is not severely compromised.

## 6. Comparison of Technological Characteristics

The technological design features of the subject bone cement and fenestrated bone screws were compared to the predicates in intended use, indications for use, design, materials, technological characteristics and performance and it was demonstrated that they are substantially equivalent.

## 7. Performance Data

Nonclinical testing was performed on the Dynamo™ Spinal Cement, Salvo® Spine System to support substantial equivalence to predicate devices. Dynamic compression bending tests (per ASTM F1717) were performed. Additionally, removal torque testing (per ASTM F543) and testing of the cement flow and bolus formation of the subject devices were performed. Axial pull-out testing was performed.

Clinical testing is not applicable.

## 8. Conclusion

The indications for use, technological characteristics, and performance testing show that the subject devices are substantially equivalent to the legally marketed predicate devices.