June 6, 2025

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

Re: K251131
Trade/Device Name: Annex® 2 Adjacent Level System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: April 11, 2025
Received: April 11, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

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)*
K251131

Device Name
Annex® 2 Adjacent Level System

Indications for Use *(Describe)*
When used with pedicle screw fixation systems, the Annex® 2 Adjacent Level 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).

The Annex® 2 Adjacent Level System can be linked to 4.75 mm, 5.5 mm, and/or 6.0 mm diameter rods of the following systems: CapSure®, Sniper® or Salvo® Spine Systems.

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.

510(k) #: K251131

510(k) Summary

Prepared on: 2025-04-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Spine Wave, Inc.
Applicant Address	Three Enterprise Drive Suite 210 Shelton CT 06484 United States
Applicant Contact Telephone	203-712-1846
Applicant Contact	Mr. Ronald Smith
Applicant Contact Email	rsmith@spinewave.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Annex® 2 Adjacent Level System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K132403	Annex® Adjacent Level System	MNH
K240685	Salvo® Spine System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The Annex® 2 Adjacent Level System consists of a selection of non-sterile, single-use locking screws, adjacent level devices, and connectors for attachment to an existing pedicle spinal fixation construct to extend a rigid spinal construct. The Annex® 2 Adjacent Level System components are provided in a variety of sizes and shapes to accommodate variations in anatomy and spacing/positioning of existing screw and rod hardware. The implant components of this system are manufactured from titanium (ASTM F67)), titanium alloy (Ti-6Al-4V ELI (ASTM F136)), and cobalt-chromium (CoCr (ASTM F1537)).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

When used with pedicle screw fixation systems, the Annex® 2 Adjacent Level 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).

The Annex® 2 Adjacent Level System can be linked to 4.75 mm, 5.5 mm, and/or 6.0 mm diameter rods of the following systems: CapSure®, Sniper® or Salvo® Spine Systems.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Annex® 2 Adjacent Level System is substantially equivalent to the predicate devices. The Annex® 2 Adjacent Level System has the

same intended use as the primary predicate. Specifically, the devices are used in thoracolumbosacral revision surgery to extend an existing pedicle spinal fixation instrumentation contruct. Therefore, the subject Annex® 2 Adjacent Level System is substantially equivalent to its predicate in intended use, and no new issues of safety and effectiveness are raised.

Technological Comparison

21 CFR 807.92(a)(6)

The Annex® 2 Adjacent Level System has technological characteristics equivalent to those of the predicate devices, including design, and material composition.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing was performed on the Annex® 2 Adjacent Level System to support substantial equivalence to legally marketed predicate devices. Static axial compression bending, static torsion testing and dynamic axial compression bending testing per ASTM F1717 was performed.

Clinical testing is not applicable.

Evaluation of the subject device performance data as compared to legally marketed predicate devices has found that the Annex® 2 Adjacent Level System is substantially equivalent.