Spine Wave, Inc.
Amy Noccioli
Sr. Regulatory Affairs Specialist
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

October 10, 2019

Re: K192526
Trade/Device Name: Spine Wave Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 12, 2019
Received: September 13, 2019

Dear Amy Noccioli:

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, Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192526

Device Name
Spine Wave® Navigated Instruments

Indications for Use *(Describe)*

The Spine Wave® Navigated Instruments are intended to be used during the preparation and placement of Spine Wave screws (Sniper® Spine System, CapSure® Spine System, Proficient® Posterior Cervical Spine System, or the Salvo™ Spine System) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. The Spine Wave® Navigated Instruments are designed for use with the Medtronic StealthStation® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192526

510(k) Summary
Spine Wave® Navigated Instruments

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1842
Telefax: 203-944-9493

Contact: Amy Noccioli

Date Prepared: October 9, 2019

2. Device Information

Trade Name: Spine Wave® Navigated Instruments
Common Name: Orthopedic Stereotaxic Instruments
Classification: Class II per 21 CFR 882.4560
Classification Name: Stereotaxic Instruments
Product Code: OLO

3. Purpose of Submission

The purpose of this submission is to gain clearance for the addition of new instruments and to expand the indications to allow use with Salvo™ Spine System screws.

4. Predicate Device Information

The Spine Wave® Navigated Instruments described in this submission are substantially equivalent to the following predicate:

Primary Predicate Device	Manufacturer	510(k) No.
Navigated Instruments	Spine Wave	K181596

5. Device Description

The Spine Wave® Navigated Instruments are reusable, manual, surgical instruments made from stainless steel. These instruments are to be used with the Medtronic StealthStation® System via the Medtronic NavLock™ Tracker to facilitate screw placement during cervicothoracic and thoracolumbosacral surgeries. New instruments are being added to allow use with Salvo™ Spine System screws.

6. Indications for Use

The Spine Wave® Navigated Instruments are intended to be used during the preparation and placement of Spine Wave screws (Sniper® Spine System, CapSure® Spine System, Proficient® Posterior Cervical Spine System, or the Salvo™ Spine System) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. The Spine Wave® Navigated Instruments are designed for use with the Medtronic StealthStation® System.

7. Comparison of Technological Characteristics

The Spine Wave® Navigated Instruments have technological characteristics similar to those of the predicate device, including intended use, performance, design, and material composition.

8. Performance Data

A dimensional analysis and characterization was performed for the new components to demonstrate substantial equivalence.

9. Conclusion

The intended use and technological characteristics show that the Spine Wave® Navigated Instruments are substantially equivalent to the predicate devices identified in this submission and do not present any new issues of safety or effectiveness.