August 18, 2025

Evolution Spine
James Mirda
Principal Engineer
2300 N. Haskell Ave
Dallas, Texas 75204

Re: K250167
Trade/Device Name: Evolution Spine Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 21, 2025
Received: July 21, 2025

Dear James Mirda:

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,

Shumaya Ali -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250167

Device Name

Evolution Spine Navigation Instruments

Indications for Use *(Describe)*

The Evolution Spine navigation instruments are indicated for use during the preparation and placement of Whistler Modular Pedicle Screw System polyaxial screws or Stowe Pedicle Screw System polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The navigation instruments are intended to be used with the Medtronic® StealthStation® S8 Navigation System (Software Version 1.3.0)., which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K250167

510(k) Summary

Prepared on: 2025-08-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Evolution Spine
Applicant Address	2300 N. Haskell Ave Dallas TX 75204 United States
Applicant Contact Telephone	901-550-3377
Applicant Contact	Mr. James Mirda
Applicant Contact Email	jmirda@evolutionspine.com
Correspondent Name	Evolution Spine
Correspondent Address	2300 N. Haskell Ave Dallas TX 75204 United States
Correspondent Contact Telephone	9015503377
Correspondent Contact	Mr. James Mirda
Correspondent Contact Email	jmirda@evolutionspine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Evolution Spine Navigation Instruments
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223649	VERTICALE® Navigation Instruments	OLO
K16120	Medtronic Navigated Instruments	HWE
K140454	Navigated CD HORIZON® SOLERA® Screwdrivers and Taps	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The Evolution Spine Navigation Instruments are reusable surgical instruments for use with the Medtronic® StealthStation® S8 Navigation System. The system is designed to assist surgeons in the precise localization of anatomical structures, preparation and placement of pedicle screw implants during spinal procedures.
The Evolution Spine navigation Instruments include awls, probes, taps and drivers. The navigated instruments are to be used with Whistler Modular Pedicle Screw System (K182478) and Stowe Pedicle Screw System (K181554).
All instruments are made of stainless steel per ASTM F899. The Evolution Spine navigation Instruments are not compatible with implants

from other manufacturers and are designed for use only with Medtronic® StealthStation® S8 Navigation System hardware and software.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Evolution Spine navigation instruments are indicated for use during the preparation and placement of Whistler Modular Pedicle Screw System polyaxial screws or Stowe Pedicle Screw System polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The navigation instruments are intended to be used with the Medtronic® StealthStation® S8 Navigation System (Software Version 1.3.0)., which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject "Indications for Use" statement is nearly identical to those of the predicate devices with only minor changes that do not impact the indicated use of the devices.

Technological Comparison

21 CFR 807.92(a)(6)

Evolution Spine Navigation Instruments is substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have substantially equivalent technological characteristics to the predicate devices through comparison of design, intended use, material composition, function, and range of sizes.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The worst-case instruments constructs were tested per ASTM F2554-18, “Standard
Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”. The worst-case construct meets and exceeds all the performance criteria identified in Kamimura et al: Accurate pedicle screw insertion under the control of a computer-assisted guiding system: Laboratory test and clinical study and ASTM F2554-18. Based upon the test data presented and comparison of features, Evolution Spine has determined that the proposed System is substantially equivalent to previously cleared systems.

Clinical testing was not necessary to demonstrate the substantial equivalence of the subject devices.

A comparison of critical dimensions was conducted to support the substantial equivalence of the subject devices.

Biocompatibility was addressed through use of idenctical manufacturing materials and processes to the devices cleared in K182478 and K181554.

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject Evolution Spine Navigation Instruments has been shown to be substantially equivalent to legally marketed predicate devices.