May 8, 2025

Altus Partners LLC.
Rand Baker
QA/RA Manager
1340 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K243419
Trade/Device Name: Altus Spine Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 4, 2025
Received: April 4, 2025

Dear Rand Baker:

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,

Tejen D. Soni -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243419

Device Name
Altus Spine Navigation System

Indications for Use *(Describe)*
The Altus Spine Navigation System reusable instruments are indicated to be used during the preparation and placement of Altus Spine Valencia Pedicle Screw System and Altus Spine Monaco Pedicle Screw System screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Altus Spine Navigation System reusable instruments are specifically designed for use with the Medtronic StealthStation® System S8, 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 for the anatomy.

• For a comprehensive summary of indications, the IFU for the specific system of use must be directly referenced: Altus Spine Valencia Pedicle Screw System / Altus Spine Monaco Pedicle Screw System.

The Altus Spine Navigation System is intended to pair with either the Altus Spine Valencia Pedicle Screw System or Altus Spine Monaco Pedicle Screw system to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The Altus Spine Navigation system may be used for noncervical pedicle fixation via posterior percutaneous approach with MIS instrumentation.

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) Summary

SUBMITTER:	Altus Partners, LLC 1340 Enterprise Drive West Chester , PA 19380 Phone: 610-356-6148 Fax: 610-300-3049
CONTACT PERSON:	Rand Baker QA/RA Manager rbaker@altus-spine.com
DATE PREPARED:	May 8, 2025
TRADE OR PROPRIETARY NAME:	Altus Spine Navigation System
PRIMARY PREDICATE DEVICES:	Medtronic Sofamor Danek, USA Inc., Navigated CD Horizon® Solera® Screwdrivers and Taps (K170679)
ADDITIONAL PREDICATE DEVICES:	Altus Spine Monaco Pedicle Screw System (K230766) Altus Spine Valencia Pedicle Screw System (K181281)
CLASSIFICATION & REGULATION #:	Class II per 21 CFR §888.4560
PRODUCT CODES:	OLO

DEVICE DESCRIPTION:

The Altus Spine Navigation System reusable instruments are surgical instruments for use with the Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. The Altus Spine Navigation System includes the following instruments dedicated to screw placement: Screwdrivers and Taps. The Altus Spine Navigation System is to be used with the following Altus Spine Systems:

- Altus Spine Valencia Pedicle Screw System
- Altus Spine Monaco Pedicle Screw System

All instruments are made of stainless steel per ASTM F899. All instruments are reusable instruments provided non sterile. The Altus Spine Navigation System instruments are not compatible with implants from other manufacturers. The Altus Spine Navigation System are designed for use only with Medtronic StealthStation® System S8 (V2.1.0) and the Medtronic NavLock® Tracker System.

INDICATIONS FOR USE:

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SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine Navigation System has the same or similar technological characteristics as the predicate instruments including design (instrument functional length and NavLock® connection feature), intended use, material composition, function, range of sizes, and sterility. The subject system shares the same principle of operation as the predicates. The subject instruments differ from the primary predicate in tip geometries and dimensions in order to accommodate the spinal screws; however, the differences are minor and do not raise any new concerns of safety or effectiveness with respect to the predicate.

PERFORMANCE DATA:

The Altus Spine Navigation System was tested side-by-side with the primary predicate device and passed recognition and location testing with the Medtronic StealthStation® System S8 navigation system via ASTM F2554. The subject device and predicate device were compared for dimensional accuracy and the critical length. The results demonstrate that the subject device is substantially equivalent to the predicate device in use and performance.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The overall technology characteristics and mechanical performance data lead to the conclusion that the Altus Spine Navigation System is substantially equivalent to the predicate device.