February 12, 2026

Medtronic Navigation, Inc.
Victoria Baldock
Senior Regulatory Affairs Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K253381
Trade/Device Name: Stealth AXiS™ Surgical System with Stealth AXiS™ Spine clinical application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 13, 2025
Received: November 14, 2025

Dear Victoria Baldock:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253381

Device Name
Stealth AXiS™ Surgical System
Stealth AXiS™ Spine Clinical Application

Indications for Use *(Describe)*

Stealth AXiS™ Surgical System

The Stealth AXiS™ Surgical System is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. The Stealth AXiS™ Surgical System is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Stealth AXiS™ Surgical System is indicated for precise robotic positioning of surgical instruments or implants during orthopedic or neurosurgery. It may be used in open, minimally invasive, and percutaneous procedures.

Stealth AXiS™ Spine Clinical Application

The Stealth AXiS™ Surgical System, with the Stealth AXiS™ Spine clinical application, is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. Their use is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

This can include procedures in adult patients, such as:
•Interbody device placement
• Pedicle screw placement
•Iliosacral screw placement

This can include the following spinal implant procedure in skeletally mature pediatric (adolescent) patients:
• Pedicle screw placement

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

February 6, 2025

I. Company: Medtronic Navigation, Inc.
200 Medtronic Drive
Lafayette, CO 80026
Telephone Number: (720) 890-3160

Contact: Victoria Baldock
Senior Regulatory Affairs Specialist
Telephone Number: (423) 863-5907
Email: tori.a.baldock@medtronic.com

Carey Brenner (Alternate)
Principal Regulatory Affairs Specialist
Telephone Number: (720) 890-2185
Email: carey.j.brenner@medtronic.com

II. Proprietary Trade Name: Stealth AXiS™ Surgical System with Stealth AXiS™ Spine Clinical Application

III. Common Name: Orthopedic Stereotaxic Instrument

IV. Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

V. Classification: Class II

VI. Product Code: OLO (Orthopedic Stereotaxic Instrument)

VII. Predicate Devices:
The legally marketed predicate and reference devices are identified below:

Subject Device	Primary Predicate Device	Secondary Predicate Device
Stealth AXiS Surgical System	Mazor X System with Software v5.2 **K251316** S.E. September 11, 2025	StealthStation S8 Platform **K162309** S.E. March 31, 2017
Stealth AXiS Spine Clinical Application		StealthStation S8 Spine Software v2.1 **K251282** S.E. October 17, 2025

VIII. Device Description:

The Stealth AXiS™ Surgical System is a computer-assisted surgery system that is composed of a platform, clinical application, surgical instruments, and a referencing system (which includes patient and instrument trackers). The system tracks the position of instruments in relation to the surgical anatomy, known as localization, and then identifies this position on preoperative or intraoperative images of a patient. The Stealth AXiS™ Surgical System supports both optical and electromagnetic (EM) localization. Localization is also called navigation.

The Stealth AXiS™ Spine clinical application helps guide surgeons during spine procedures. Patient images can be displayed by the Spine clinical application from a variety of perspectives (axial, sagittal, coronal, oblique) and 3-dimensional (3D) renderings of anatomical structures can also be displayed. During navigation, the system identifies the tip location and trajectory of the tracked instrument on images and models the user has selected to display. The surgeon may also create and store one or more surgical plan trajectories before surgery and simulate progression along these trajectories. During surgery, the clinical application displays how the actual instrument tip position and trajectory relate to the plan, helping to guide the surgeon along the planned trajectory. While the surgeon's judgment remains the ultimate authority, real-time positional information obtained through the Stealth AXiS™ Surgical System can serve to guide this judgment.

With the addition of the Stealth AXiS™ Autopilot to the Stealth AXiS™ Core, the Stealth AXiS™ Surgical System becomes a robotic-assisted surgery system.

IX. Indications for Use:

Stealth AXiS™ Surgical System

The Stealth AXiS™ Surgical System is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. The Stealth AXiS™ Surgical System is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Stealth AXiS™ Surgical System is indicated for precise robotic positioning of surgical instruments or implants during orthopedic or neurosurgery. It may be used in open, minimally invasive, and percutaneous procedures.

Stealth AXiS™ Spine Clinical Application

The Stealth AXiS™ Surgical System, with the Stealth AXiS™ Spine clinical application, is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. Their use is indicated for medical conditions in which the use of stereotactic surgery may be

appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

This can include procedures in adult patients, such as:

- Interbody device placement
- Pedicle screw placement
- Iliosacral screw placement

This can include the following spinal implant procedure in skeletally mature pediatric (adolescent) patients:

- Pedicle screw placement

X. Comparison of Technological Characteristics:

A comparison of the technological characteristics of the subject, primary predicate, and secondary predicate is provided in the tables below.

Table 1. *Stealth AXiS Surgical System Platform and Accessories Substantial Equivalence Comparison*

Technological Characteristic	**Stealth AXiS Surgical System – Platform & Accessories (Subject)**	**Mazor X Stealth Edition – Platform & Accessories (K251316 (Primary Predicate)**	**Stealth Station S8 – Platform & Accessories (K162309) (Secondary Predicate)**
Product Code, Class	OLO Class II	OLO and LLZ, Class II	OLO, PGW and HAW Class II
Regulation Number	882.4560	882.4560	882.4560
Intended Use	The Stealth AXiS Surgical System is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures.	Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in open or minimally invasive or percutaneous procedures.	The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures.
Indications for Use	The Stealth AXiS Surgical System is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. The Stealth AXiS Surgical System is indicated for medical conditions in which the use of	Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in open or minimally invasive or percutaneous procedures. Mazor X 3D imaging capabilities provide processing and conversion of	The StealthStation System is intended as an aid for precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where

Technological Characteristic	Stealth AXiS Surgical System – Platform & Accessories (Subject)	Mazor X Stealth Edition – Platform & Accessories (K251316 (Primary Predicate)	Stealth Station S8 – Platform & Accessories (K162309) (Secondary Predicate)
	stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. The Stealth AXiS Surgical System is indicated for precise robotic positioning of surgical instruments or implants during orthopedic or neurosurgery. It may be used in open, minimally invasive, and percutaneous procedures.	2D fluoroscopic projections from standard C-Arm into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefit from generated 3D images of high contrast objects. Mazor X navigation tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient.	reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Anatomical Sites	Spine	Spine	Cranial, Spine and ENT
Mechanism of Action	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical, electromagnetic, and hybrid navigation. Motorized positioning of the Surgical Arm with tool guide through 7 axes.	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical navigation. Motorized positioning of the Surgical Arm with tool guide through 6 axes.	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical and electromagnetic navigation.
System	• Workstation Cart • Camera Cart • Autopilot (Robotic Cart + Robotic Arm + RIST, including the 3D camera) • Planning Station • Device Accessories	• Workstation • Surgical System 3Define Camera: SR300 model • Bed Mounted Unit (e.g., Bed Frame) • Mazor X Navigation Camera and accessories • Device accessories for spine application	• Workstation Cart • Camera Cart • Planning Station • Device accessories
Optical Technology	Manufacturer: NDI Localizer: Vega VT	Manufacturer: NDI Localizer: Vega ST	Manufacturer: NDI Localizer: Vega XT
Electromagnetic Technology	Manufacturer: Identical (Medtronic Navigation, Inc.) Localizer: AxiEM III Emitter Types: Side		Manufacturer: Identical (Medtronic Navigation, Inc.) Localizer: AxiEM III Emitter Types: Side, Flat

Table 2. *Stealth AXiS Spine Clinical Application Substantial Equivalence Comparison*

Technological Characteristic	Stealth AXiS Surgical System – Platform & Accessories (Subject)	Mazor X Software v5.2 (K251316 (Primary Predicate)	StealthStation S8 Spine Software v2.1 (K162309) (Secondary Predicate)
Product Code	OLO	OLO, LLZ	OLO
Regulation Number	882.4560	882.4560	882.4560
Intended Use	The Stealth AXiS Surgical System, with the Stealth AXiS Spine clinical application, is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures.	Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in open or minimally invasive or percutaneous procedures.	The StealthStation System, with StealthStation Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures.
Indications for Use	The Stealth AXiS Surgical System, with the Stealth AXiS Spine clinical application, is intended for precise positioning of surgical instruments and as an aid for precisely locating anatomical structures in open, minimally invasive, and percutaneous procedures. Their use is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy. This can include procedures in adult patients, such as: • Interbody device placement • Pedicle screw placement • Iliosacral screw placement This can include the following spinal implant procedure in skeletally mature pediatric (adolescent) patients: • Pedicle screw placement	Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in open or minimally invasive or percutaneous procedures. Mazor X 3D imaging capabilities provide processing and conversion of 2D fluoroscopic projections from standard C-arms into a volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefit from generated 3D images of high contrast objects. Mazor X navigation tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this	The StealthStation System, with StealthStation Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures in adult and skeletally mature pediatric (adolescent) patients. Their use 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 the spine, can be identified relative to images of the anatomy. This can include the following spinal implant procedures in adult patients, such as:

Technological Characteristic	Stealth AXiS Surgical System – Platform & Accessories (Subject)	Mazor X Software v5.2 (K251316 (Primary Predicate)	StealthStation S8 Spine Software v2.1 (K162309) (Secondary Predicate)
		position on diagnostic or intraoperative images of a patient.	• Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement This can include the following spinal implant procedures in skeletally mature pediatric (adolescent) patients: • Pedicle Screw Placement
Stealth AXiS Operating Principle (Tracking Method)	Optical (infra-red) Hybrid (Optical + EM)	Optical (infra-red)	Optical (infra-red)
System Accuracy Requirements	Under representative worst-case Configuration, the Stealth AXiS System has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.	Mazor X System mean accuracy <1.5mm Navigation Accuracy mean positional error <2mm and mean trajectory error of 2°. Mazor X will also provide Facet Decortication depth accuracy within 1.5mm.	Under representative worst-case Configuration, the StealthStation S8 Spine software v2.1, has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.
Target Patient Population	Adult and Skeletally Mature Pediatric (Adolescent) Orthopedic Patients	Orthopedic Patients	Adult and Skeletally Mature Pediatric (Adolescent) Orthopedic Patients
Imaging Modalities	CT and Fluoro based imaging X-ray based imaging	CT and Fluoro based imaging X-ray based imaging (Planning)	X-Ray Based Imaging
Registration Features	-3D-to-Fluoro Registration -Automatic 3D Image Registration (Automatic O-arm Registration) -Segmental Tracking	-CT-Fluoro Merge Registration - Automatic 3D Image Registration (Scan and Plan, Automatic Registration)	-PointMerge Registration -SurfaceMerge Registration -FluoroMerge Registration -Automatic 2D Image -- Registration

Technological Characteristic	Stealth AXiS Surgical System – Platform & Accessories (Subject)	Mazor X Software v5.2 (K251316 (Primary Predicate)	StealthStation S8 Spine Software v2.1 (K162309) (Secondary Predicate)
			-Automatic 3D Image Registration -StealthAiR Spine Automatic Registration
Spine Segmentation	Manual Automatic	Manual Automatic	
Planning Features	-Plan Entry and Target Selection -3D Model Building	- Plan Entry and Target Selection - 3D Model Building	-Plan Entry and Target Selection -3D Model Building
Medical Device Interfaces	- O-arm Imaging System - 2D C-Arm - 3D C-Arm	- O-arm Imaging System - 2D C-Arm - 3D C-Arm	-O-arm Imaging System -Ziehm Vision FD Vario 3D C-Arm -ISO-C 3D C-Arm -Ziehm Vision RFD 3D C-arm -Orbic 3D C-Arm
View/Display Features	-Look Sideways -3D -Anatomic Orthogonal -Trajectory 1 and 2 -Trajectory Guidance -Look Ahead -Probe's Eye -AP and Lateral -Maximum Intensity Projection -Video Input	-Look Sideways -3D -Trajectory 1 and 2 Trajectory Guidance -Camera Mode -AP and Lateral -Synthetic AP and Lateral -Maximum Intensity Projection	-Look Sideways -3D -Anatomic Orthogonal -Trajectory 1 and 2 Trajectory Guidance -Look Ahead -Probe's Eye -AP and Lateral -Synthetic AP and Lateral -Maximum Intensity Projection -Video Input
Robotic Control	Trajectory Guidance	Trajectory Guidance	

XI. Discussion of Nonclinical Testing:

The testing conducted on the Stealth AXiS Surgical System with Stealth AXiS Spine clinical application included:

- Under representative worst-case configuration, the Stealth AXiS Surgical System with Stealth AXiS Spine clinical application has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error of ≤ 2.0 degrees.
- Platform and software verification and validation testing verified the product requirements are met, and the device performs as intended.
- Hardware verification and validation testing verified the product requirements are met, and the hardware performs as intended.

- Summative usability validation was performed by representative users in a simulated clinical environment (cadaver). The summative evaluations demonstrated the Stealth AXiS Surgical System with Stealth AXiS Spine clinical application for the intended user, uses, and use environments.
- Electrical Emissions and Immunity 4th edition testing provided confirmation that the Stealth AXiS Surgical System platform conforms to AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601;1:2005/AMD2:2021 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005 + AMD1:2012 + AMD2:2020).
- Electrical, Mechanical, and Thermal Safety testing confirmed that the Stealth AXiS Surgical System platform conforms to IEC 60601-1-2:2014+ A1:2020 – Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests.

XII. Discussion of Clinical Testing:

A retrospective clinical evaluation of published literature was performed on the StealthStation Navigation System and Mazor System for use in the skeletally mature pediatric (adolescent) patient population.

XIII. AI-enabled Device Summary

Automatic Planning

The auto-planning feature in the Stealth AXiS Spine clinical application uses Artificial Intelligence (AI) to automate pedicle screw placement for spinal surgeries, providing patient-specific recommendations for select Medtronic screw types. Clinical users retain full control to review, modify, or override AI-generated plans before approval.

This feature employs a Siamese Neural Network to compare candidate screw placements to expert standards, using inputs from deep learning-based spine segmentation and rule-based spinal features algorithms. Training data consisted of expert screw placements from Surgical Support Technicians, enabling the model to identify solutions closely aligned with expert decisions.

For validation, test data was strictly separated from training data by site and included scans stratified by surgical approach and vertebra. The model outputs screw placement that would be most similar to the expert's screw placements, aiding user evaluation, while final decisions remain with the clinician.

The AI model is locked and does not update after deployment.

Automatic Spine Segmentation

The Automatic Spine Segmentation feature in the Stealth AXiS Spine clinical application uses deep learning AI to automatically segment vertebrae from CT and CBCT (O-arm) images, supporting planning and guidance for spine surgery. Users review and can modify AI-generated segmentations to maintain clinical control in the application.

This locked UNet-based model distinguishes vertebrae in 3D images, with its vertebral segmentation dependent on image quality and then user verification. The network was trained and validated using internal and public datasets. employing patch-wise training and early stopping to prevent overfitting.

Model performance and verification and validation test data was separated from training data. The model performance was evaluated by comparing the AI-generated segmentations to clinician-reviewed ground truth, ensuring statistical confidence.

The model is locked and does not update after deployment.

XIV. Conclusion:

The Stealth AXiS Surgical System with Stealth AXiS Spine clinical application has been shown through comparison, testing, and clinical literature to be substantially equivalent to the identified primary and secondary predicates.