September 11, 2025

Mazor Robotics Ltd.
Anat Marom
Senior Regulatory Affairs specialist
1 HaEshel Street (Building C), Caesarea Buisness Park
Caeasarea, 3079830
Israel

Re: K251316
Trade/Device Name: Mazor X System / Mazor X Stealth Edition
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: August 11, 2025
Received: August 11, 2025

Dear Anat Marom:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251316

Please provide the device trade name(s).

Mazor X System/ Mazor X Stealth Edition

Please provide your Indications for Use below.

The 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 a 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 benefits from generated 3D imaging of high contrast objects.

The 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary – K251316

Applicant name: Mazor Robotics Ltd.

1 HaEshel Street (Building C)

Caesarea business Park 3079830, Israel

Contact person: Name: Anat Marom

Role: Sr. Regulatory Affairs Specialist

Email: anat.marom@medtronic.com

Phone: +972-506874994

Date Prepared: September 11, 2025

Name of Device: Mazor X Stealth Edition

Classification Name: Stereotaxic instrument

Classification Code: OLO (primary) and LLZ

Device class: II

Regulation number: 21 CFR 882.4560

Panel: Orthopedic

Predicate Devices: Mazor X System (Mazor X Stealth Edition) (K230064)

Intended Use / Indications for Use

The 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 a processing and conversion of 2D fluoroscopic projections from standard C Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

The 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.

Device Description

The Mazor X system combines robotic trajectory guidance with navigated surgical instruments (either guided or free hand navigation) to enable the surgeon to precisely position surgical instruments and/or implants according to predefined planning. With the imaging capabilities of the system, the user can also visualize the implants on the patients CT. Same as the predicate device the modified Mazor X consists of a workstation with dedicated software, the surgical system, navigation camera, accessories, instruments and disposable kits. The modified Mazor X, the subject of this 510(k) application, introduces software and hardware modifications to the Mazor X System cleared in 510(k) K230064.

Technological Characteristics

The *modified* Mazor X device is similar in its technological features to its predicate device, the cleared Mazor X. Both the subject and predicate systems combine *robotic* and *navigation* technologies to enable the precise positioning and tracking of surgical instruments or spinal implants during general spinal surgery. Both systems allow registration of image data with patient anatomy by registering the pre-operative CT scan to the intra-operative fluoroscopic scans, and by localizing the position of the 3D patient volume to the robotic system. In both systems, the positioning of surgical instruments and their trajectories are guided by the system in accordance with the planning conducted by the surgeon on the pre-operative CT image. In both systems, the navigation feature provides the option of tracking the surgical instruments during the procedure. Both systems include very similar hardware and software components, including the workstation, the surgical system, navigation camera, accessories, instruments, and disposable kits. The modifications to the cleared Mazor X System, that are the subject of this premarket application, include software enhancements to enable extended functionality (in registration and planning stages), compatibility with additional, previously cleared, surgical tools and some minor hardware changes.

The minor differences in the technological characteristics between the modified Mazor X and its predicate device do not raise different questions of safety or efficacy. The performance bench testing and Human Factors validation, provided with this premarket application, demonstrate that the modified Mazor X is as safe and effective as its predicate devices.

Comparison of the Proposed Mazor X to the Cleared Mazor X System (K230064) is provided below:

Table 1: Comparison of the Proposed Mazor X to the Cleared Mazor X System (K230064)

Technological Characteristic	**Mazor X System Mazor Robotics Ltd.**	**Mazor X System Mazor Robotics Ltd. K230064 (predicate device)**	**Comparison**
Product Code, Class	OLO and LLZ, Class II	OLO and LLZ, Class II	Identical
Indications for Use	The 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 a 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 benefits from generated 3D imaging of high contrast objects. The 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.	The 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 a 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 benefits from generated 3D imaging of high contrast objects. The 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.	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Target Population	Orthopedic patients	Orthopedic patients	Identical
Anatomical Sites	Spine	Spine	Identical
Environment Used	Hospital setting (operating room)	Hospital setting (operating room)	Identical
Main system components	The Mazor X System consists of the following components: • Workstation • Surgical System 3Define Camera: SR300 model • Bed Connecting Unit (e.g., Bed Frame) • Device accessories for spine application • Mazor X Navigation Camera and accessories	The Mazor X System consists of the following components: • Workstation • Surgical System 3Define Camera: SR300 model • Bed Connecting Unit (e.g., Bed Frame) • Device accessories for spine application • Mazor X Navigation Camera and accessories	Similar. X-Eye camera was removed, and its function to intra-operatively position the Surgical Arm for fluoro acquisition purposes was replaced by "Drag AP DOT" feature.
Mechanism of Action	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical navigation. Motorized positioning of the Surgical Arm (spine) with tool guide through 6 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 (spine) with tool guide through 6 axes.	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Compatibility with Medtronic authorized instruments and tools	Mazor X is compatible with the following Medtronic tools and instruments: • Medtronic Spine instruments (K182121) • Medtronic Navigation NavLock Trackers (K182104) • Medtronic Stealth-Midas and Stealth Midas MR8 navigated drill systems (K160713, K183644) • Medtronic navigated surgical instruments - Trials trackers, Inserters and Disc Prep Instruments (K131425, K163581, K150231) and Medtronic Pedicle Probe (K050438) • Medicrea UNiD Analyzer (K212005) • Stealth-Midas Rex Drill System (K202552) • Medtronic Navigated Anterolateral Disc Prep Instruments (K211441) • Medtronic Adaptix Interbody System with Titan nanoLOC Surface Technology (K201267) • Medtronic CD HORIZON™ Spinal System (K211596) • Medtronic Catalyft PL (K214011)	Mazor X is compatible with the following Medtronic tools and instruments: • Medtronic Spine instruments (K182121) • Medtronic Navigation NavLock Trackers (K182104) • Medtronic Stealth-Midas and Stealth Midas MR8 navigated drill systems (K160713, K183644) • Medtronic navigated surgical instruments - Trials trackers, Inserters and Disc Prep Instruments (K131425, K163581, K150231) and Medtronic Pedicle Probe (K050438) • Medicrea UNiD Analyzer (K212005) • Stealth-Midas Rex Drill System (K202552) • Medtronic Navigated Anterolateral Disc Prep Instruments (K211441) • Medtronic Adaptix Interbody System with Titan nanoLOC Surface Technology (K201267) • Medtronic CD HORIZO N™ Spinal System (K211596)	Similar. Compatibility with additional, cleared to market, Medtronic authorized instruments and tools using the same navigation technology, enabling tracking the position of the instruments in relation to the surgical anatomy and identify this position on the patient images. The compatibility with additional, cleared to market, tools, does not change the system indications for use, design or its principles of operation and do not raise new questions of safety and efficacy.

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
	• Medtronic Anteralign TL and Voyager FNS (K214011) • Anteralign LS (K222383), Capstone PTC implants and Enhanced (size 36, length of 36 mm) Capstone implants (K172199). • Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology (K212524) • ModuLeX FAS drivers, FAS screws and Osteogrip Shanks (K231184) • ModuLeX FNS Screw set (K232141) • ModuLeX Degen Scoli (K233951) • Adaptix™ PEEK Interbody System (K241605)	• Medtronic Catalyft PL (K214011) • Medtronic Anteralign TL and Voyager FNS (K214011) • Anteralign LS (K222383), Capstone PTC implants and Enhanced (size 36, length of 36 mm) Capstone implants (K172199).	
Features	The Mazor X System consists of the following features: • Preoperative planning and operation • Advanced 3D Visualization (volume rendering) • Robotic guidance and optical navigation of surgical tools	The Mazor X System consists of the following features: • Preoperative planning and operation • Advanced 3D Visualization (volume rendering) • Robotic guidance and optical navigation of surgical tools	Identical
Imaging Modalities	• CT and Fluoro based imaging • X-ray based imaging (Planning)	• CT and Fluoro based imaging • X-ray based imaging (planning)	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Registration Features	• CT-Fluoro Merge Registration • Automatic 3D Image Registration (Scan and Plan, Automatic Registration)	• CT-Fluoro Merge Registration • Automatic 3D Image Registration (Scan and Plan)	Similar. The Automatic Registration with O-arm is an enhancement to the Automatic 3D Image Registration process.
Planning Features	• Plan Entry and Target Selection • 3D Model Building	• Plan Entry and Target Selection • 3D Model Building	Similar. Three enhancements were introduced to the Plan Entry and Target Selection capabilities: 1. 2D Automatic Measurements: incorporates a locked machine learning based algorithm that automatically detects anatomical landmarks, used for calculating anatomical measurements, for the automatic pre-op planning capability. 2. Plan Assist feature, a locked machine learning based algorithm, enhances the initial screw placement by considering user preferences and clinical constrains, thus providing clinically acceptable initial screw placement. 3. Support for additional pre-bent rods type - Medtronic CD

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
			Horizon (ModuleX) short pre-bent rods for planning and repositioning screws also in the Scan & Plan workflow, in addition to CT-FL workflow. All three (3) planning enhancements described above do not change the system's indications for use, have no effect on system's accuracy and do not raise new safety and effectiveness issues.
Medical Device Interfaces	• O- arm Imaging System • 2D C-Arm • 3D C-Arm	• O- arm Imaging System • 2D C-Arm • 3D C-Arm	Identical
Dimensions	Workstation: 1.85 x 1.20 x 0.64 m (6.07 x 3.94 x 2 ft) Surgical System: 0.92 x 0.63 x 0.58 m (3.02 x 2.07 x 1.9 ft) Mazor X Navigation Camera (NDI Vega Polaris: 1.9 x 0.65 x 0.61 m (6.2x2.1 x 2 ft)	Workstation: 1.85 x 1.20 x 0.64 m (6.07 x 3.94 x 2 ft) Surgical System: 0.92 x 0.63 x 0.58 m (3.02 x 2.07 x 1.9 ft) Mazor X Navigation Camera (NDI Vega Polaris: 1.9 x 0.65 x 0.61 m (6.2x2.1 x 2 ft)	Similar The removal of the X-eye camera (a component of the surgical system) has a negligible impact on the system dimensions.
Weight	• Workstation - 185 kg (408 lbs)	• Workstation - 185 kg (408 lbs)	Similar

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
	• Surgical System – 25 kg (55.1 lbs) • Mazor X Navigation Camera (NDI Vega Polaris) - 75Kg (165.3lbs)	Surgical System – 25 kg (55.1 lbs) • Mazor X Navigation Camera (NDI Vega Polaris) - 75Kg (165.3lbs)	The removal of the X-eye camera (a component of the surgical system) has a negligible impact on the system weight.
Performance	• 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.	• 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.	Identical
Human Factors	The Mazor X System simplifies the planning and surgical procedure (pre-intra-operative planning) and provides the user with additional imaging modalities (3D Define Scan, Auto Segmentation Process, etc.). Mazor X Planning facilitates performing measurements and calculating angles within a specific spinal region of interest, in accordance with standard classifications.	The Mazor X System simplifies the planning and surgical procedure (pre-intra-operative planning) and provides the user with additional imaging modalities (3D Define Scan, Auto Segmentation Process, etc.). Mazor X Align facilitates performing measurements and calculating angles within a specific spinal region of interest, in accordance with standard classifications.	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Cybersecurity	Mazor X system contains external wired communication interface (ethernet). Mazor X system is developed in accordance with the Cybersecurity design controls to ensure Mazor X Cybersecurity and maintain safety and effectiveness, similarly to the currently cleared device.	Mazor X system contains external wired communication interface (ethernet). Mazor X system is developed in accordance with the Cybersecurity design controls to ensure Mazor X Cybersecurity and maintain safety and effectiveness, similarly to the currently cleared device.	Identical
Standards Met	IEC 62304	IEC 62304	Identical
Materials	• Ultem 1000HU • Carbon Fiber Zacton 350 • Ketron LSG PEEK Natural Black/ TECAPEEK • Stainless Steel • Aluminum 6061 • Polyethylene • MedikoteTM C12 (Me-DLC)	• Ultem 1000HU • Carbon Fiber Zacton 350 • Ketron LSG PEEK Natural Black/ TECAPEEK • Stainless Steel • Aluminum 6061 • Polyethylene • MedikoteTM C12 (Me-DLC)	Identical
Biocompatibi-lity	Materials are biocompatible	Materials are biocompatible	Identical
Compatibility With the Environment and Other Devices	The Mazor X is compliant with the IEC 60601-1-2 (EMC Compatibility) standard.	The Mazor X is compliant with the IEC 60601-1-2 (EMC Compatibility) standard.	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Sterility	No new sterilization methods or products have been introduced in the Mazor X. The reusable accessories are sterilized by steam sterilization, single-use disposable kits by gamma radiation, and sterile covers (e.g., Sterile Sleeve for Surgical Arm) by ETO sterilization. Mazor X navigation tools are sterilized with the Medtronic Sofamor Danek spine instruments(K182121) and Medtronic Navigation NavLock tools (K182104).	No new sterilization methods or products have been introduced in the Mazor X. The reusable accessories are sterilized by steam sterilization, single-use disposable kits by gamma radiation, and sterile covers (e.g., Sterile Sleeve for Surgical Arm) by ETO sterilization. Mazor X navigation tools are sterilized with the Medtronic Sofamor Danek spine instruments(K182121) and Medtronic Navigation NavLock tools (K182104).	Identical
Electrical Safety	• Power Requirements: • 110-120 VAC, 60 Hz • 220-240 VAC, 50 Hz • 100 VAC, 50/60 Hz • Maximum Power = 1000 VA The Mazor X System is compliant with the IEC 60601-1 (Electrical Safety) std.	• Power Requirements: • 110-120 VAC, 60 Hz • 220-240 VAC, 50 Hz • 100 VAC, 50/60 Hz • Maximum Power = 1000 VA The Mazor X System is compliant with the IEC 60601-1 (Electrical Safety) std.	Identical
Mechanical Safety	The Mazor X System is compliant with the IEC 60601-1 (Electrical Safety) standard.	The Mazor X System is compliant with the IEC 60601-1 (Electrical Safety) standard.	Identical
Chemical Safety	Not Applicable	Not Applicable	Identical
Thermal Safety	The Mazor X System is compliant with the IEC 60601-1 standard.	The Mazor X System is compliant with the IEC 60601-1 standard.	Identical
Radiation Safety	The Mazor X System is compliant with the IEC 60601-1-2 (EMC) standard.	The Mazor X System is compliant with the IEC 60601-1-2 (EMC) standard.	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K230064 (predicate device)	Comparison
Laser Safety	The Mazor X System is compliant with IEC 60825-1 (2014) (Safety of laser) standard.	The Mazor X System is compliant with IEC 60825-1 (2014) (Safety of laser) standard.	Identical

Performance Testing

The following testing was conducted to evaluate the device:

a) Software major level of concern verification and validation testing was conducted as required by IEC 62304 and FDA Guidance on General Principles of Software Validation, January 11, 2002.

b) Bench testing was conducted to verify that the design outputs meet the design inputs. The functionality of the new or modified features was tested to ensure that system requirements, software requirements and user needs were met as defined. Specifically, the Automatic registration feature and the new machine-learning based features (2D Automatic Measurements and Plan Assist) and the X-Eye camera removal were verified and validated through testing.

AI-enabled device software functions

1. 2D Automatic Measurements

The software incorporates the 2D Automatic Measurements feature which automatically detects key spinopelvic landmarks and produces spinopelvic measurements on AP and LAT X-rays images. The feature utilizes two locked AI algorithms: the Endplate detection algorithm and the Femoral head detection algorithm.

Table 2: 2D Automatic Measurements algorithms development: demographic, technical and reference standard characteristics

	Endplate detection development	**Femoral heads detection development**
Sample size per view	2327 AP images, 2651 LAT images.	2233 LAT images
Gender	42% female, 32% male, 26% unknown	45% female, 29% male, 26% unknown
Age groups	10% Children & adolescents, 31% Adults, 27% Geriatric, 32% unknown	16% Children & adolescents, 25% Adults, 26% Geriatric, 33% unknown
Image quality distribution	19% good, 32% medium, 49% poor	13% good, 24% medium, 63% poor
Image quality definition	Image quality was categorized as Good, Medium, or Poor based on contrast, bone delineation, and artifact/noise levels. Images rated Poor were excluded from the validation dataset.	
Reference standard type & process	Endplate line and Circle femoral heads annotations were performed by trained labelers within a quality-controlled environment. In case of multiple annotations, they were aggregated. More than 65% of the data was reviewed by U.S. certified spine surgeons and radiologists.	

A non-clinical evaluation of the endplate and femoral heads detection accuracy was conducted as part of the verification effort.

A clinical evaluation of 13 spinopelvic parameters' measurements accuracy was conducted as part of the validation effort.

Table 3: 2D Automatic Measurements algorithms clinical testing process: demographic, technical, reference standard and statistical analysis characteristics

	Spinopelvic parameters' measurements accuracy
Sample size per view	146 AP images, 253 LAT images (for all spinopelvic parameters). Each spinopelvic parameter had its own sample size ranging from 24 images to 126 images.
Gender	67% female, 30% male, 3% unknown
Age groups	43% Children & adolescents, 33% Adults, 13% Geriatric, 11% unknown
Image quality distribution	~30% good, ~70% medium (average across all spinopelvic parameters).
Image quality definition	Image quality was categorized as Good, Medium, or Poor based on contrast, bone delineation, and artifact/noise levels. Images rated Poor were excluded from the validation dataset.
Reference standard type & process	Each spinopelvic parameter annotations were comprised of endplate line annotations, endplate endpoint annotations, and/or femoral head circle annotations performed by Three U.S board certified radiologists using the Mazor X device and compared to the AI measurements value.
Test statistics	1. Single measurement absolute agreement intraclass correlation coefficient (ICC) was used to assess agreement the AI measurement results and the reference standard. The acceptance criterion of the ICC of least 0.75 with a 95% confidence level was achieved for all spinopelvic measurements. 2. An F test was conducted to statistically demonstrate that the ICC was statistically larger than 0.75. For all spinopelvic measurements, the resulting p-value was below 0.05. 3. Bland Altman analysis – for all spinopelvic measurements, the 95% limits of agreement were in range of a defined clinical range.

Non-clinical verification and clinical validation datasets were independent from the development dataset, with data source site-level separation to ensure data independence.

Out of scope for the 2D Automatic Measurements Feature: implants or foreign objects, images with a quality rank of "poor" or "very poor", and unique spinal conditions (revisions, fractures, tumors, hemivertebrae).

2. Plan Assist

The software incorporates the Plan Assist feature, which automatically suggests initial pedicle screw positions during spinal surgery planning using locked AI algorithm

Table 4: Plan Assist algorithm development process: demographic, technical and reference standard Characteristics

	Plan Assist Algorithm Development (Training + Tuning)
Sample size	The development dataset contains 160 studies (101 3D CT scans, 59 3D O-arm scans), 942 vertebrae, 5,795 unique screw placements and over 23,000 screw plannings.
Gender	25% female, 11% male, 64% unknown
Age groups	14% children and adolescents, 13% Adults, 9% Geriatric, 64% unknown
Image quality distribution	47% good, 52% medium, 1% poor.
Image quality definition	Image quality was categorized as Good, Acceptable, Poor, or Very Poor based on contrast, bone delineation, and presence of artifacts and noise. Images rated Very Poor were excluded from the training dataset.
Reference standard type & process	Annotations for Pedicle screw planning were performed by 34 qualified Surgical support technicians. The reference Screw planning ("annotation") was manually performed using a released Mazor X software.

A clinical evaluation of screw placement was conducted as part of the validation effort.

Table 5: Plan Assist algorithm clinical testing - demographic, technical, reference standard, and statistical analysis characteristics

	Plan Assist Algorithm Testing (Clinical Validation)
Sample size per view	326 screw plans from 25 spine images.
Gender	28% female, 12% male, 60% unknown
Age groups	16% children and adolescents, 12% Adults, 12% Geriatric, 60% unknown
Image quality distribution	56% good, 44% medium
Image quality definition	Image quality was classified as Good, Acceptable, Poor, or Very Poor based on contrast, bone delineation, and artifact/noise levels. Images rated Poor or Very Poor were excluded from the validation dataset.
Test statistics	Each AI-generated screw was evaluated by three experts for clinical acceptability. The True Positive Rate (TPR) exceeded 80% with 95% confidence, meeting the acceptance criteria.

Development and validation datasets were separated at the site level to ensure data independence. Out of scope for the Plan Assist Feature: O-Arm scans in the range of T1-T8, implants or foreign objects of any kind, unique spinal conditions (revisions, fractures, tumors, hemivertebrae), and images with a quality rank of "poor" or "very poor".

Conclusion

The modified Mazor X is as safe and effective as the cleared Mazor X. The modified Mazor X has the same intended use and indications for use and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the modified Mazor X and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the modified Mazor X is as safe and effective as its predicate device. Thus, the Mazor X is substantially equivalent.