April 7, 2023

Mazor Robotics Ltd.
Marina Shkedy
Sr. Regulatory Affairs Specialist
1 HaEshel Street (Building C)
Caesarea Business Park, 3079830
Israel

Re: K230064
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: December 29, 2022
Received: January 9, 2023

Dear Marina Shkedy:

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,

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)*
K230064

Device Name
Mazor X System (Mazor X Stealth Edition)

Indications for Use *(Describe)*
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.

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)

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510(k) Summary

Applicant name: Mazor Robotics Ltd.

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Date Prepared: April 6th, 2023

Name of Device: Mazor X System (Mazor X Stealth Edition)

Classification Name: Stereotaxic instrument

Classification Code: OLO and LLZ

Device class: II

Regulation number: 882.4560

Panel: Orthopedic

Predicate Devices: Mazor X System (Mazor X Stealth Edition) (K203005)

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) K203005.

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, compatibility with additional, previously cleared, surgical tools and some minor hardware changes.

However, as explained in more detail below, these differences do not raise new or different questions of safety or effectiveness since the principal technology remains very similar and, in both instances, the key question is whether the robotic and navigation functionalities are accurate. The bench performance testing and human factors validation demonstrated that the modified Mazor X is safe and effective as the predicate device.

Comparison of the Proposed Mazor X to the Cleared Mazor X System (K203005) is provided below:

Table 0-1: Comparison of the Proposed Mazor X to the Cleared Mazor X System (K203005)

Technological Characteristic	**Mazor X System** **Mazor Robotics Ltd.**	**Mazor X System** **Mazor Robotics Ltd.** **K203005 (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	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	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
	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.	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.	
Target Population	Orthopedic patients	Orthopedic patients	Identical
Anatomical Sites	Spine	Spine	Identical
Environment Used	Hospital setting (operating room)	Hospital setting (operating room)	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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	Identical
Mechanism of Action	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical	Computer assisted Stereotaxy: Instrument position and trajectory calculation based on image data & instrument tracking based on optical	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
	navigation. Motorized positioning of the Surgical Arm (spine) with tool guide through 6 axes.	navigation. Motorized positioning of the Surgical Arm (spine) with tool guide through 6 axes.	
Compatibility with Medtronic 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)	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)	Similar. Compatibility with additional, cleared to market, Medtronic 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.

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
	• 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 navigated surgical instruments - Trials trackers, Inserters and Disc Prep Instruments (K131425, K163581, K150231) and Medtronic Pedicle Probe (K050438)	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. K203005 (predicate device)	Comparison
	• Medtronic Adaptix Interbody System with Titan nanoLOC Surface Technology (K201267) • Medtronic CD HORIZO N™ Spinal System (K211596) • 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).		

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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) • Mazor X Align • Robotic guidance 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
Registration Features	• CT-Fluoro Merge Registration • Automatic 3D Image Registration (Scan and Plan)	• CT-Fluoro Merge Registration • Automatic 3D Image Registration (Scan and Plan)	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
Planning Features	• Plan Entry and Target Selection • 3D Model Building	• Plan Entry and Target Selection • 3D Model Building	Identical
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)	Identical
Weight	• Workstation - 185 kg (408 lbs) • Surgical System – 25 kg (55.1 lbs)	• Workstation - 185 kg (408 lbs) • Surgical System – 25 kg (55.1 lbs)	Identical

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
	• Mazor X Navigation Camera (NDI Vega Polaris) - 75Kg (165.3lbs)	• Mazor X Navigation Camera (NDI Vega Polaris) - 75Kg (165.3lbs)	
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°.	Similar. A requirement for robotic depth mean accuracy (along the trajectory) was added for the Facet Decortication procedure since in the FD procedure the robotic arm serves as a mechanical stopper. The criterion for accuracy is the same as in the cleared device <1.5 mm.

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
			A series of performance bench testing demonstrated that the absolute robotic depth error is smaller than ±1.5 mm and that the overall system accuracy is equivalent to the predicate device system accuracy. In addition, the navigation accuracy was tested and found to be equivalent to the navigation accuracy performance of the predicate device (mean positional error <2mm

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
			and mean trajectory error of 2°). The performance tests demonstrated that the modified Mazor X device keeps the same robotic and navigation accuracy as in the predicate device and the addition of accuracy requirement along the trajectory doesn't raise new questions of safety and efficacy.

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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. K203005 (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

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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	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. K203005 (predicate device)	Comparison
and Other Devices			
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

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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 • Maximum Power = 1000 VA The Mazor X System is compliant with the IEC 60601-1 (Electrical Safety) std.	Extended power range to support additional markets
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

Technological Characteristic	Mazor X System Mazor Robotics Ltd.	Mazor X System Mazor Robotics Ltd. K203005 (predicate device)	Comparison
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
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

Substantial Equivalence

The modified Mazor X is as safe and effective as the cleared Mazor X. The modified Mazor X has the same intended uses 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.

Non-Clinical Performance Data

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 updated Spine Segmentation feature, the addition of Facet Decortication capability, the integration compatibility of the Medicrea UNiD (K212005) and the Planning mode UX / UI improvements were verified and validated through testing.

Conclusions

The modified Mazor X is substantially equivalent to its predicate, 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 is predicate device, raise no new issues of safety or effectiveness. Non-clinical performance data demonstrate that the Mazor X performs as expected and in a manner that is substantially equivalent to its predicate device. Thus, the Mazor X is substantially equivalent.