Mazor Robotics Ltd.
% Ahava Stein
Regulatory Affairs Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as St.
Kfar Saba, 44425 Il

November 2, 2018

Re: K182077
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, HAW, LLZ
Dated: July 23, 2018
Received: August 1, 2018

Dear Ahava Stein:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S
Digitally signed by Jesse Muir -S
Date: 2018.11.02 11:25:49 -04'00'

For:
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182077

Device Name
Mazor X System (Mazor X Stealth Edition)

Indications for Use *(Describe)*

Indications for Use The Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain 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.

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.

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SUMMARY OF SAFETY AND EFFECTIVENESS

K182077

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Mazor Robotics Ltd.
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Caesarea Park North 3088900,
Israel

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
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Kfar Saba 4442520,
Israel

2. Date Prepared: July 24, 2018

3. Device Name Mazor X

Proprietary Name: Mazor X System (Mazor X Stealth Edition)

Common Name: Combination of:
1. Stereotaxic instrument; and
2. System, Image Processing, Radiological

FDA Classification Name: 21 CFR 882.4560; Stereotaxic instrument

FDA Classification: Class II, Product Code OLO, HAW and LLZ

4. Predicate Devices

The Mazor X is substantially equivalent to the following device:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics Ltd.	Mazor X System	K180307	April 30, 2018
Medtronic Navigation Inc.	StealthStation System with the S8 Spine Software	K170011 and K162309	May 1, 2017 March 31, 2017

5. Device Description

The Mazor X System integrates a new Navigation feature, which enables tracking compatible spine instruments. The previously cleared Mazor X System enables mechanical positioning of a tool or instrument and determining its orientation and trajectory. The new Navigation feature tracks the position of compatible surgical instruments in or on the patient anatomy during surgery and continuously updates the instrument position on the image of the patient's anatomy. The modified Mazor X System can operate with or without the Navigation feature.

6. Indications for Use

The Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It may be used in either 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.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Mazor X.

8. Performance Testing

The following performance tests were conducted on the modified Mazor X System with the Navigation feature.

- Mazor X System Accuracy Workflow Validation Test (VV-07444)

The key performance testing to validate the modified Mazor X System navigation feature consisted of navigation accuracy testing. The navigation accuracy validation included testing the overall navigation accuracy under worst-case scenario navigation tool positioning. The overall accuracy under worst-case scenario navigation tool positioning calculated the position and trajectory errors.

Minor modifications were made to the released Mazor X System and accessories and therefore, the following validation tests were conducted:

- Mazor X System Surgical System Test (MCP0721-01)
- Mazor X System Surgical Arm Test (MCP0695-01)
- Mazor X System Accuracy (CT-Fluro, Scan & Plan) Tests) (CT-Fluro - MCP0881-01 & Scan & Plan - MCP0882-01)
- Mazor X System Accessories Tests Summary (MCP0885-01)
- Cadaver validation activities (GC17021, TP-GC17021)

The tests performed to validate the modifications to the previously cleared Mazor X System included testing the modified Surgical System and the modified Surgical Arm. The modified Mazor X System was also tested to ensure that the software changes did not affect the previously cleared robotic guidance trajectory accuracy (i.e., $\leq$ 1.5mm), in the CT-Fluro and Scan & Plan workflows, following the software modifications. Testing was also performed for the new and modified Mazor X System accessories.

The Mazor X System software with the navigation feature was underwent software validation according to FDA Guidelines for Software Validation and the following standard:

- IEC 62304 Medical Device Software: Software Life Cycle Processes (2015)

The modified Mazor X System underwent the following testing according to international and FDA recognized standards:

- AAMI/ANSI ES 60601-1:2005/(R):2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment – Part 1:

General Requirements for Basix Safety and Essential Performance (IEC 60601-1:2005, Mod) 2012

- IEC 60601-1-2:2014 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility

9. Technological Characteristics Compared to Predicate Device

The intended use and technological characteristics of the modified Mazor X System are substantially equivalent to the intended use and technological characteristics of the previously cleared Mazor X System (K180307) and the FDA cleared, predicate StealthStation Surgical System with S8 Spine Software (K170011 & K162309). The performance of the modified Mazor X System is substantially equivalent to the performance of the FDA cleared, Mazor X System, as demonstrated by the software validation and functional performance testing. The functional performance testing also demonstrated that the navigation capabilities of the Mazor X System are substantially equivalent to the navigation capabilities of the predicate StealthStation Surgical System with S8 Spine Software (K170011 & K162309).

10. Conclusion

The performance testing and comparison to the predicate devices demonstrate that the Mazor X system is as safe, as effective and performs as well as the legally marketed Mazor X System (K180307) and the StealthStation Surgical System (K170011 & K162309) predicate devices. Therefore, the Mazor X system is substantially equivalent to the Mazor X System and the StealthStation Surgical System with S8 Spine Software.