May 8, 2020

Mazor Robotics Ltd.
Shiran Conforti
RA Manager
5 Shacham St. North Industrial Park
Caesarea, 3079567
Israel

Re: K200935
Trade/Device Name: Mazor X
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: April 7, 2020
Received: April 8, 2020

Dear Shiran Conforti:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200935

Device Name
Mazor X

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 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

K200935

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Mazor Robotics Ltd.
PO Box 3104,
5 Shacham St.,
Caesarea Park North 3079567,
Israel

Official Correspondent
Shiran Conforti
Mazor Robotics Ltd.
PO Box 3104,
5 Shacham St.,
Caesarea Park North 3079567,
Israel

2. Date Prepared: April 07, 2020

3. Device Name Mazor X

Proprietary Name: Mazor X

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 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 (Mazor X Stealth Edition)	K182077	November 2, 2018

5. Device Description

The modified Mazor X hosts guidance for spine procedures and intra-operative 3D image processing capabilities. It enables the surgeon to precisely position surgical instruments and/or implants. The planning of the surgical procedure and virtual placement of surgical instruments and/or implants (e.g., a screw) can be achieved through pre-operation planning based on the patient's CT scan or intra-operative planning based on Mazor X 3D Scan image or on a 3D image uploaded from an external 3D image acquiring system. The Mazor X enables accurate deployment of surgical accessories in the precise anatomical location according to predefined planning. With the imaging capabilities of the system, the user can also visualize the implants on the patients CT. The Mazor X is a device modification of the original Mazor X System cleared in 510(k) K182077.

6. 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.

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 performed on the modified Mazor X system:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and the IEC 62304 Standard for Medical Device Software - Software Life Cycle Processes. The software validation tests demonstrate that the Mazor X software version meets the design requirements. Test cases were designed for testing procedure simplicity, system startup, security, user interfaces, diagnostics and error handling, performance and robustness, installation, and database.
- Hardware changes verification: the system parts and accessories that were modified were tested to verify that they meet the requirements. The test protocols that were used are identical to the test protocols used to verify and validated the same parts for the cleared Mazor X.

9. Technological Characteristics Compared to Predicate Device

The device modifications included modified labeling, modified software with minor software changes and a slightly modified Mazor X System (minor hardware changes). The software changes included SW optimization within the established specifications, enhanced functionalities as well as screen enhancements (graphical enhancements and enhanced information presented on screen). The modified Mazor X workstation, Bed Frame and Mazor X Bone Mount interface - are very similar to the cleared Mazor X workstation Bed Frame and Mazor X Bone Mount interface with some minor technical and design improvements.

The modifications do not adversely affect the safety, effectiveness and performance of the Mazor X system. The Mazor X system was tested according to the aforementioned validation and performance tests and found compliant.

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., of the Mazor X system are substantially equivalent to the predicate device cited above.

10. Conclusion

The performance testing and comparison to the predicate device demonstrate that the Mazor X system is as safe, as effective and performs as well as the legally marketed Mazor X System predicate device. Therefore, the Mazor X system is substantially equivalent to the Mazor X System cleared under K182077.