Mazor Robotics Ltd.
％ Ahava Stein
Regulatory Affairs Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as St., Beit Hapaamon Suite 102
Kfar Saba, 4442520
Israel

Re: K172522
 Trade/Device Name: Mazor X
 Regulation Number: 21 CFR 882.4560
 Regulation Name: Stereotaxic Instrument
 Regulatory Class: Class II
 Product Code: OLO, HAW, LLZ
 Dated: August 16, 2017
 Received: August 21, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K172522

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 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.

Type of Use (Select one or both, as applicable)

- [x] 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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FORM FDA 3881 (8/14)
SUMMARY OF SAFETY AND EFFECTIVENESS

K172522
(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address: Mazor Robotics Ltd.
PO Box 3104,
5 Shacham St.,
Caesarea Park North 3088900,
Israel

Official Correspondent: Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata’as St. (Beit Hapaamon, Suite 102)
Kfar Saba 4442520,
Israel

Date Prepared: August 16, 2017

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, HAW and LLZ

4. Predicate Devices

The Mazor X is substantially equivalent to the following device:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
<th>510(k)</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mazor Robotics Ltd.</td>
<td>Mazor X System</td>
<td>K163221</td>
<td>April 04, 2017</td>
</tr>
<tr>
<td>MedTech Inc.</td>
<td>Rosa Surgical System</td>
<td>K101791</td>
<td>September 23, 2010</td>
</tr>
</tbody>
</table>
5. Device Description
The Mazor X hosts guidance for spine and brain procedures and intra-operative 3D image processing capabilities. It enables the surgeon to precisely position surgical instruments and/or implants (in spinal surgery). 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.

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.

7. Performance Standards
There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Mazor X.
8. **Performance Testing**

No additional performance tests were required for the modified Mazor X system:

9. **Technological Characteristics Compared to Predicate Device**

The modifications do not adversely affect the safety, effectiveness and performance of the Mazor X system. The intended use and 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 devices cited above.

10. **Conclusion**

The comparison to the predicate devices demonstrate that the Mazor X system is substantially equivalent to the predicate devices.