DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 17, 2015

Mazor Robotics Ltd.
% Moshe Rosenberg
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as St. (POB 124)
Kfar Saba, 4442520
ISRAEL

Re: K152041
Trade/Device Name: Renaissance X System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW, LLZ
Dated: September 24, 2015
Received: October 5, 2015

Dear Moshe Rosenberg:

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 Parts 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 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" (21CFR 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 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 yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152041

Device Name
Renaissance X System

Indications for Use *(Describe)*
The Renaissance X System 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.

Renaissance 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)*

☒ 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

K152041

[redacted]

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Mazor Robotics Ltd.
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Official Correspondent
Ahava Stein
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20 Hata'as St. (Beit Hapaamon, Suite 102)
Kfar Saba 4442520,
Israel

2. Date Prepared: September 24, 2015

3. Device Name Renaissance X System

Proprietary Name: Renaissance X System

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 modified Renaissance X System is substantially equivalent to the following devices:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics Ltd.	Renaissance X System	K140167	September 10, 2014
Mazor Robotics Ltd.	Renaissance System with Brain Application	K120812	July 12, 2012

5. Device Description

The modified Renaissance X System 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 Renaissance X 3D Scan image or on a 3D image uploaded from an external 3D image acquiring system. The modified Renaissance X System 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 modified Renaissance X System is a device modification of the original Renaissance X System cleared in 510(k) K140167 and the original Renaissance System with Brain Application cleared in 510(k) K120812.

6. Indications for Use

The modified Renaissance X System 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.

Renaissance 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 modified Renaissance X System.

8. Performance Testing

The following Performance tests were performed on the modified Renaissance X System:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrate that the modified software version meets its design requirements.
- Stability Testing - these tests demonstrate the mechanical integrity of the modified Renaissance X System. The results show that the system's design meets the functional requirements of the system with the same safety margins as the predicate devices.
- Usability Testing – these tests demonstrate that the Renaissance X System has maintained the required usability, as specified in the device design requirements. These tests have established that the system is easy to use, that the surgical procedure can be completed successfully without any interruptions, problems, safety or other issues.

9. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the modified Renaissance X System are substantially equivalent to the predicate devices cited above.