XACT Robotics Ltd.
℅ Mr. Jonathan S. Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

July 9, 2020

Re: K201586
Trade/Device Name: XACT Robotic System, ACE Model
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 11, 2020
Received: June 11, 2020

Dear Mr. Kahan:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K201586

Device Name
XACT Robotic System, ACE Model

Indications for Use *(Describe)*

The XACT Robotic System, ACE Model is a user-controlled positioning system intended to assist in the planning and advancement of an instrument during Computed Tomography (CT) guided percutaneous procedures. The system is used for trajectory planning and is intended to assist the physician in positioning of an instrument, such as a needle, where CT imaging is used for target trajectory planning and intraoperative tracking.

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
XACT Robotic System, ACE Model
K201586

Submitter

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Contact Person: Chen Levin, CEO

Date Prepared

June 11, 2020

Name of Device

XACT Robotic System, ACE Model

Common or Usual Name

CT Stereotactic Accessory

Classification Name

21 CFR 892.1750; Computed tomography X-ray system

Regulatory Class

Class II

Product Code

JAK

Predicate Devices

XACT Robotics Ltd., XACT Robotic System (K191332)

Device Description

The XACT Robotic System is a user-controlled positioning system intended to assist in the planning and advancement of instruments during Computed Tomography (CT) guided percutaneous procedures. The system is used for trajectory planning based on CT images and is intended to assist the physician in positioning of an instrument, such as a needle, and reviewing instrument position during advancement to the target. The system guides (i.e., positions and steers) the instrument according to a predefined trajectory. The physician controls advancement of the instrument along the trajectory using a foot pedal. The system also allows for monitoring of motion associated with respiration during the procedure.

The XACT Robotic System, ACE Model comprises the following main components:

- XACT Robot which is placed on the patient and includes the robot positioning unit & the insertion module assembly
- XACT Console which includes a Control Unit, central computer (in the Control Unit) and monitor workstation for user trajectory planning, user interface and review of instrument position

Intended Use / Indications for Use

The XACT Robotic System is a user-controlled positioning system intended to assist in the planning and advancement of an instrument during Computed Tomography (CT) guided percutaneous procedures. The system is used for trajectory planning and is intended to assist the physician in positioning of an instrument, such as a needle, where CT imaging is used for target trajectory planning and intraoperative tracking.

Summary of Technological Characteristics

The XACT Robotic System, ACE Model allows for planning of percutaneous CT-guided procedures and tracking and positioning of the instrument during the procedure.

Both the XACT Robotic System, ACE Model and its predicate, the XACT Robotic System, are designed and intended for planning and positioning of instruments for percutaneous intervention under imaging guidance of CT scanners. The systems position the instrument according to a predefined trajectory following a registration process between the device's coordinate system and real-time CT images. The user advances the instrument through a foot pedal.

Both systems are comprised of the same components and accessories, though the ACE Model incorporates minor modifications. XACT Robotic System, ACE Model, incorporates a refined aesthetic with new covers, along with minor updates to the electronics and cabling to address the more compact designed. The Console is also redesigned such that a laptop is no longer provided for the user interface as the ACE Model incorporates a central computer, and a monitor + mouse are used for user interface for ease of use and improved appearance. The system software for the ACE Model does not introduce any new features or significant changes to existing features.

Performance Data

The following performance/safety tests were conducted with the XACT Robotic System, ACE Model:

- Mechanical Accuracy
- Registration Precision
- CT Phantom Accuracy
- Robot Rigidity
- Axes Mapping
- Complete SW STD
- Electrical safety in accordance with IEC 60601-1
- Electromagnetic compatibility in accordance with IEC 60601-1-2

Conclusions

The XACT Robotic System, ACE Model has the same intended uses and indications for use, technological characteristics and principles of operation as its predicate device. The limited differences in the structural characteristics of the components do not affect its safety and effectiveness when used as labeled. In addition, the minor differences between the XACT Robotic System, ACE Model and its predicate do not raise different issues of safety or effectiveness. Performance data demonstrate that the XACT Robotic System, ACE Model is as safe and effective as the predicate device. Thus, the XACT Robotic System, ACE Model is substantially equivalent.