May 13, 2022

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

Re: K221116
Trade/Device Name: XACT ACE Robotic System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: April 15, 2022
Received: April 15, 2022

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221116

Device Name
XACT ACE Robotic System

Indications for Use *(Describe)*
The XACT ACE 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.

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

K221116 **XACT Robotics' XACT ACE Robotic System**

Submitter

XACT Robotics, Ltd.
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Contact Person: Chen Levin, CEO

Date Prepared: April 15, 2022

Name of Device:

XACT ACE Robotic System

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 Robotic System, ACE Model (K201586)

Purpose of the Special 510(k) Notice

The XACT ACE Robotic System is a modification to the XACT Robotic System, ACE Model, which involves expansion of the list of instruments supported by the device during CT-guided percutaneous procedures, to include four types of ablation probes. To accommodate these ablation probes, an additional configuration of the Instrument Insertion Kit is introduced, to secure the ablation probe's handle, which is different than a biopsy introducer's head.

Intended Use

The XACT ACE 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.

Device Description

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

- XACT ACE Robot which is placed on the patient and includes the robot positioning unit & the insertion module assembly
- XACT ACE 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.

Technological Characteristics

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

Both the XACT ACE Robotic System and its previously cleared predicate 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 several checkpoints using a foot pedal.

Both systems are comprised of the same components and accessories. Further, the system software for the XACT ACE Robotic System does not introduce any new features or significant changes to existing features. Although there are minor differences between the subject and predicate device, namely supporting use of the device in the positioning of ablation probes, these differences do not raise new or different questions of safety or efficacy.

Performance Data

The performance testing included compatibility testing between the instruments (ablation probes), the Instrument Insertion Kit securing them and the robotic system. According to a predefined protocol – "Needle Properties", the physical characteristics of each probe were first measured including their "Max. Curvature", which defines the maximum, non-vertical force that can be applied without deforming the probe. Then, the robotic system was used to steer each of the probes to a variety of targets while closely monitoring the performance of the Instrument Insertion Kits and the overall accuracy in reaching the targets. This verification test demonstrated that Instrument Insertion Kit

efficiently secures the probes and advance them to the target without any physical damage to the probes. Furthermore, all relevant physical characteristics were adequately measured and configured in the robotic system allowing steering to the targets while meeting performance specifications.

Then, the XACT ACE Robotic System was validated in a simulated clinical environment, in a CT suite using a specific phantom. This test was performed to verify it steers the compatible listed ablation probes to a variety of targets ("organs" and target depths), while meeting similar performance characteristics (tip-to-target average accuracy) compared to biopsy introducers. All trajectories included several checkpoints and performance was evaluated based on CT images obtained during the procedures. Test results demonstrated that the device meets all of its performance characteristics with no changes to the clinical workflow.

Conclusions

The XACT ACE Robotic System has the same intended uses and indications for use, technological characteristics and principles of operation as its predicate device. The limited differences in enabling support of ablation probes in addition to biopsy introducers do not affect the safety or effectiveness of the device. Performance tests demonstrates that the XACT ACE Robotic System is as safe and effective as the predicate device. Thus, the XACT ACE Robotic System is substantially equivalent.