September 23, 2022

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

Re: K213759
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: August 26, 2022
Received: August 26, 2022

Dear Jonathan 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
DHT8B: Division of Imaging Devices
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K213759

Device Name
XACT Robotic System, ACE Model

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# K213759 510(k) SUMMARY

## XACT Robotic Ltd.'s XACT Robotic System, ACE Model

**Submitter**

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Contact Person: Tsvia Erlich, Vice President, RA & Clinical Affairs

**Date Prepared:**

August 24, 2022

**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 Robotic System, ACE Model (K201586)

**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 or a pushbutton on the control room console. 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

**Intended Use / Indications for 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.

**Summary of 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. The current version of the XACT ACE Robotic System includes a modification to an optional, remote-control accessory (ACE Xtend). The ACE Xtend allows the control of the system and the advancement of an instrument from the control room. The use of ACE Xtend is limited to facilities that have appropriate view from the control room, of both, the patient and the XACT ACE Robot mounted on the patient.

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 (or advancement button if controlling the XACT ACE Robot with ACE Xtend from the control room). Both systems have the same intended use/indication for use, target patient population, compatible imaging system, clinical procedure and compatible type of instruments.

Both systems are comprised of the same components and accessories. The XACT ACE Robot and Console are the same. The Remote-Control box of the XACT ACE Robotic System (ACE Xtend) and its previously cleared predicate are located in the control room of the CT suit and duplicates the Emergency Stop Button and the monitor while the subject device also duplicates the Console GUI and the needle advancement button (Foot Pedal of the predicate device).

Further, the system software for the XACT ACE does not introduce any new features or significant changes to existing features. The software was updated to facilitate the use of the ACE Xtend and prevent the control from both units at the same time. Although there are minor differences between the subject and predicate device, namely updated labeling to incorporate the results of the abdominal and lung clinical studies, as well as updated remote control of the XACT ACE Robot from the control room, these differences do not raise new or different questions of safety or efficacy. Thus, the current XACT ACE Robotic System, is substantially equivalent to its predicate.

**Performance Data**

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

- Electrical safety (per IEC 60601-1)
- EMC (per IEC 60601-1-2)
- Steering Accuracy test evaluated system performance including tip-to-target accuracy when controlled from the ACE Xtend in a simulated clinical setup,
- Software verification and validation

**Clinical Data**

The XACT ACE Robotic System has been assessed in two clinical trials evaluating the device in both abdominal and lung CT-guided percutaneous procedures.

The abdominal study (NCT03008603) was held at 2 centers. Study population consisted of 60 completers, of which 33 (55%) were men and 27 (45%) women, average age was 66 ± 14.3 years (range: 35-89). The average steering time was 8.91±5.05 min. All procedures completed with the ACE system reached the target in one needle insertion.

The Lung study (NCT04651517) was held at 2 clinics in the US. Study population consisted of 20 patients 10 men (50%) and 10 women (50%). The average age was 73.4 ± 6.5 years (63-85). Lesions were distributed throughout each lobe of the lung. Skin to lesion distance was less than 8 cm in 14 patients (70%) and between 8-12 cm in the remaining 6 patients (30%). 6 lesions (30%) were smaller than one (1) cm, 14 (70%) were larger than one cm. The average steering time was 6.7±2.9 min There was one, mild, device related adverse events (skin scratch) which resolved without treatment and no device related serious adverse events.

Clinical data in lung procedures confirm the performance and safety of the device, supporting the same performance profile for the device in other CT guided percutaneous procedures. These data demonstrate that the device can be used for planning and navigating an instrument

(e.g. biopsy introducer) to the target site meeting the system's accuracy specifications with minimal adverse events.

**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 the labeling and remote operation of the device do not affect the safety or effectiveness of the device. Clinical data 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.