October 3, 2019

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

Re: K191332
Trade/Device Name: XACT Robotic System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: September 4, 2019
Received: September 4, 2019

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,

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)*

K191332

Device Name

XACT Robotic System

Indications for Use *(Describe)*

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.

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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510(k) SUMMARY
XACT Robotic System (K191332)

Submitter

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Contact Person: Chen Levin, CEO

Date Prepared:

September 4, 2019

Name of Device:

XACT 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

iSYS Medizintechnik GmbH iSYS 1 (K131433)
Perfint Healthcare Pvt. Ltd. Maxio (K132108)

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 comprises the following main components:

- XACT Robot Positioning Unit & Insertion Module Assembly which is placed on the patient
- XACT Control Unit (Central Computer)
- XACT Computer Work Station which includes the user interface for trajectory planning and review of instrument position
- XACT System Cart

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 allows for planning of percutaneous CT-guided procedures and tracking and positioning of the instrument during the procedure.

Both the XACT System and the cleared iSYS 1 predicate device are designed to provide positioning of instruments for percutaneous intervention under imaging guidance from 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. In achieving this, both the XACT Robotic System and the iSYS 1 System comprise similar components, namely a control unit, a bed/table, floor or patient mount, a robotic positioning unit and tool guide adapter and insertion module.

The XACT Robotic System robot positioning unit is placed directly on the patient in the region of interest for the percutaneous procedure, whereas the iSYS 1 System is placed on the bed/table using various adapters.

While the iSYS 1 System is only used to initially position the instrument prior to insertion into the patient and the insertion of the instrument is completed manually by the physician holding the instrument, the XACT Robotic System Insertion Module Assembly includes a jig which holds the instrument. Advancement of the instrument is controlled by the physician depressing a foot pedal to move the needle forward with the XACT Robotic System with the robot positioning unit making adjustments to the positioning of the instrument to ensure that the instrument remains on the physician defined trajectory path.

The XACT Robotic System also includes software for planning the instrument trajectory overlaid on CT images. The iSYS 1 System is used with separately cleared planning software to perform this function, though the cleared Perfint Maxio device includes its own planning software.

Performance Data

The following performance/safety tests were conducted with the XACT Robotics System:

- Mechanical Accuracy in accordance with the ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems
- Registration Precision in a simulated clinical environment under CT guidance
- CT Phantom Accuracy to evaluate device performance and system accuracy under simulated clinical conditions under CT guidance.
- Rigidity of the system under different weight loads
- Axes Mapping to evaluate the performance specifications of each of the axes of movement when individually operated
- Needle Properties Testing to evaluate the mechanical strength of compatible needles under forces which may be applied by the XACT Robot during insertion
- Body Contour & Movement/Respiration Synchronization to evaluate compatibility with different body contours and that the movement sensor is synchronized with patient breathing motions
- System Lifetime Testing
- Electrical safety in accordance with IEC 60601-1
- Electromagnetic compatibility in accordance with IEC 60601-1-2
- Biocompatibility in acordance with ISO 10993 for all patient-contacing componnets of the system

Pre-clinical animal testing was conducted on the XACT Robotic System to demonstrate the safety and effectiveness of the device. The study in a porcine model evaluated the accuracy of the XACT system as determined by the measurement of the distance from the target and reporting on adverse events. A total of 40 interventional procedures were performed in different body organs while animals were under general anesthesia. The XACT system reached the target in all of the 40 interventional procedures. The average accuracy of the system was 1.41mm ± 0.94mm.

The results of the testing demonstrate that the XACT System meets its specifications and that CT-guided interventional procedures can be performed safely and successfully consistent with the target accuracy specification.

Preliminary clinical data, to supplement the bench and preclinical animal testing and confirm the safety and performance of the system was gathered in 2 clinical centers, where the XACT Robotic System was used to plan an instrument trajectory and advance the instrument to the target in subjects undergoing CT-guided procedures in the abdominal area. Out of the 31 cases from an interim set of subjects where an instrument was inserted using the XACT Robotic System, the device successfully reached the target in 27 cases. In 4 out of the 31 subjects, the procedure was completed successfully with manual insertion according to routine clinical procedure. The system met its predefined specifications for use to guide and advance an instrument during CT-guided interventional procedures. There were no serious adverse events reported for any of the subjects.

Conclusions

The XACT Robotic System has the same intended uses and similar indications for use,

technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the XACT Robotic System and its predicate devices do not raise different issues of safety or effectiveness. Preclinical performance data demonstrate that the XACT Robotic System meets its defined specifications and that it is as safe and effective as the predicate devices. Preclinical and clinical performance with the device further supports its substantial equivalence to the predicates, providing evidence that the XACT Robotic System can be used to assist in the planning and advancement of an instrument during CT-guided percutaneous procedures with no serious adverse events specific to use of the system. Thus, the XACT Robotic System is substantially equivalent.