February 24, 2022

Quantum Surgical SAS
% Elise Lagacherie
Quality Assurance and Regulatory Affairs Director
ZAC Eureka
1000 rue du Mas de Verchant
Montpellier, 34000
FRANCE

Re: K211645
Trade/Device Name: Epione
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 19, 2022
Received: January 21, 2022

Dear Elise Lagacherie:

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
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211645

Device Name
EPIONE

Indications for Use *(Describe)*
The EPIONE device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments, as well as in verification of instrument position during Computed Tomography (CT) guided percutaneous procedures.
During the planning phase, the desired instrument placement and performance is defined relative to the target anatomy. During the guidance phase, the device enables to monitor respiratory levels and verify patient position prior to instrument advancement. During the assessment phase, the achieved instrument placement and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data.
The device is indicated for use in liver ablation procedures under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G by physicians trained for CT procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K211645
510(k) SUMMARY

Date prepared: 23, February 2022

Submitter

Quantum Surgical SAS
1000 rue du mas de Verchant
34000 Montpellier
France

Contact Person:
Elise Lagacherie, Quality & Regulatory Affairs Director
e.lagacherie@quantumsurgical.com

Device:

Name of Device: EPIONE™
Common or Usual Name: Computer assisted Surgical System.
Classification Name: Computed tomography X-ray system (21 CFR 892.1750)
Regulatory Class: II
Product Code: JAK

Predicate Device
MAXIO (JAK, K132108), Perfint Healthcare Pvt. Ltd.,

Reference Device:
CAS-One IR (JAK, K152473), CAScination AG

Device Description

The EPIONE device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments, as well as in verification of instrument position during Computed Tomography (CT) guided percutaneous procedures.

During the planning phase, the desired instrument placement and performance is defined relative to the target anatomy. During the guidance phase, the device enables to monitor respiratory levels and verify patient position prior to instrument advancement. During the assessment phase, the achieved instrument placement and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data.

The device is indicated for use in liver ablation procedures under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G by physicians trained for CT procedures.

The EPIONE device consists in the following components:

Robot cart	This mobile equipment can be moved in and out of the intervention room and is positioned next to the patient. The cart carries a robotic arm including a force sensor assembly allowing handguiding of the robotic arm by the user. The robotic arm movements are enabled by the user using a footswitch. The robot cart also embeds the electronic systems required to power and operate the robot arm.

Display cart	This mobile equipment can be moved in and out of the intervention room and is positioned next to the operator. The cart carries a touchscreen to operate the system.
Navigation cart	This mobile equipment can be moved in and out of the intervention room and is positioned next to the table. The cart carries a navigation camera.
EPIONE™ software	A software provides the step-by-step workflow assistance for intervention planning and intraoperative positioning of the robotic arm for instruments placement and post-operative assessment.
EPIONE instruments	Needle guide Patient reference Navigation probe

Indications for Use

The EPIONE device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments, as well as in verification of instrument position during Computed Tomography (CT) guided percutaneous procedures.

During the planning phase, the desired instrument placement and performance is defined relative to the target anatomy. During the guidance phase, the device enables to monitor respiratory levels and verify patient position prior to instrument advancement. During the assessment phase, the achieved instrument placement and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data.

The device is indicated for use in liver ablation procedures under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G by physicians trained for CT procedures.

Comparison of Technological Characteristics with the predicate device

	EPIONE	**MAXIO predicate device**
Intended use / Indication for Use	The EPIONE device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments, as well as in verification of instrument position during Computed Tomography (CT) guided percutaneous procedures. During the planning phase, the desired instrument placement and performance is defined relative to the target anatomy. During the guidance phase, the device enables to monitor respiratory levels and verify patient position prior to instrument advancement. During the assessment phase, the achieved instrument placement and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data. The device is indicated for use in liver ablation procedures under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G by physicians trained for CT procedures.	MAXIO is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments during Computed Tomography (CT) guided percutaneous procedures. MAXIO permits physician verification of patient position prior to needle advancement and monitoring of respiratory levels during the procedure. Image registration and overlay tools available in MAXIO are intended to provide guidance to the user during planning and instrument placement. MAXIO is indicated for use with rigid straight instruments such as needles and probes used in Computed Tomography (CT) guided percutaneous interventional procedures performed by physicians trained for CT procedures on organs and anatomical structures in the thorax, abdomen and pelvis.
Patient Anesthesia Conditions	For use under general anesthesia conditions	For use under local to general anesthesia conditions

	EPIONE	MAXIO predicate device
Intra-interventional Planning	Physician defines trajectory per an entry point and a target point on CT images.	Physician defines trajectory per an entry point and a target point on CT images.
Interventional instruments	Rigid straight interventional instruments such as needles and probes for ablation from 11G to 19G.	Rigid straight interventional instruments such as needles, probes for biopsy, ablation and drainage from 11G to 21G.
Needle configuration and performance	• Needle selection among a list of predefined needles • Manufacturer defined performances (e.g. ablation zones).	• Needle selection among a list of predefined needles • Manufacturer defined performances (e.g. ablation zones). • User-defined performances (e.g. ablation zones).
Needle guidance	• Robotic arm with needle guide is positioned on the desired trajectory as was planned on the intra-interventional CT images. • Instrument (e.g. needle) is then manually advanced through the guide on the planned trajectory.	• Robotic arm with needle guide instrument is positioned on the desired trajectory as was planned on the intra-interventional CT images. • Instrument (e.g. needle) is then manually advanced through the guide on the planned trajectory.
Patient registration	Automatic patient location to image registration per array of markers on a patient reference instrument placed on the patient's skin and included in the CT-scan images and which are located using an optical tracking system.	The location of the robotic workstation is located to a fixed established reference position relative to the C-arm and bed per the use of a docking mat and calibration process performed during the initial workstation installation.
Patient Registration verification	The navigation probe is pointed to pre-identified points on the patient (skin markers) to verify their relative locations.	Skin markers are placed on the patient and included in the CT-scan and located when planning. Then before needle placement, it is verified using a laser system that the patient has not moved by verifying that the locations of the skin markers are still in the same location as when scanned. In addition, table markers on the C-arm are also used to verify also per a laser cross-hairs that the relative locations of the C-arm and robot workstation have not changed from the original installation.
Respiratory Motion Management	Respiratory motion control using breath-hold Measurement of apnea reference level during the intra-interventional planning CT imaging. Live display of respiratory level using the markers / patient reference placed on the patient and visual comparison with the reference level during needle guidance.	Respiratory motion control using breath-hold. Measurement of apnea reference level during the intra-interventional planning CT imaging. Live display of respiratory level using a respiratory belt mounted on the patient (Medspira Breath-Hold for Interventional Radiology) and visual comparison with the reference level during needle guidance.
Intra-interventional verification	Verification CT Image registration with planning CT to compare achieved needle position to planned needle trajectory.	Verification CT Image registration with planning CT to compare achieved needle position to planned needle trajectory.
Post-procedure verification	Register intra-interventional CT series with post procedure CT series to display planned target position on Post-procedure CT image.	Register intra-interventional CT series with post procedure CT series to display planned target position on Post-procedure CT image.

The comparisons between the EPIONE and the predicate determined that:

- The EPIONE device has the same general intended use as the predicate. The indications for use of the EPIONE is for liver ablations as in the predicate except that the predicate has a wider indication to also include other procedures and anatomical areas. The EPIONE is therefore equivalent to the predicate in this respect within its indications for use in liver ablations.
- The EPIONE device is limited for use for patients under general anesthesia as in the predicate except that the predicate allows also for local anesthesia conditions. The EPIONE device is therefore equivalent to the predicate within its use under general anesthesia conditions.

- The EPIONE device is compatible for use with interventional instruments with diameters ranging from 11G to 19G as compared to the predicate with a wider range of 11G to 21G. Given that the proposed EPIONE range is within that of the predicate, the EPIONE device is therefore equivalent to the predicate within its narrower range.
- The EPIONE device was shown to have equivalent technological characteristics to the predicate including a robotic arm to position the needle guide per the planned trajectory. An important difference is that the EPIONE additionally implements an optical tracking system to both register and track the patient location and instrumentation to ensure correct placement of the needle relative to the CT based planned trajectory. The predicate alternately utilizes a locating docking mat and location calibration process at installation to provide for a fixed known location of the C-arm, and a laser system to thereafter ensure that the patient location has not changed. However, this different technological approach in the EPIONE is, along with other related differences in instrumentation for use with the tracking system, is supported by an equivalent implementation of an optical tracking system in the reference device, the CAS-One IR, for the same purposes and the same intended use as the EPIONE. This should then not raise any new questions of safety or effectiveness.

Summary of Non-Clinical Performance Data:

The following nonclinical performance testing was conducted to establish substantial equivalence and to verify that the EPIONE device will perform safely and effectively per its intended use:

- Overall System Accuracy Tests
- Respiratory Monitoring Effectiveness Tests
- Needle Bending Test Study
- Positional accuracy testing in accordance with the *ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*
- Electrical Safety Tests, in accordance with IEC 60601-1
- Electromagnetic Compatibility Tests, in accordance with IEC 60601-1-2
- Biocompatibility Tests, in accordance with standard ISO 10993 for patient contacting components
- Cleaning and Sterilization Validation Tests, for the instrument reprocessing
- Usability Testing, in accordance with IEC 62366-1:2015 and the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices*.

A preclinical animal study on the liver was conducted on porcine models using the EPIONE device to demonstrate safety and effectiveness of the device. The study evaluated the accuracy, safety, and feasibility of robotically assisted CT-guided needle placement in the liver of an in-vivo model (with breathing movements) with the EPIONE device. A total of 36 needle placements were performed in the liver. The average accuracy of the system demonstrates that the EPIONE device is safe and effective for CT-guided needle placement in the liver.

Additionally, Software design and verification and validation testing was completed in compliance with the FDA guidance "*Content of Premarket Submissions for Software Contained in Medical Devices",* the IEC 62304 Standard "Medical Device Software – Life Cycle Process", as well as FDA cybersecurity premarket guidance document "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*".

The performance testing of the EPIONE device demonstrated that it should be as safe and as effective as the predicate device.

Clinical study

A multi-center, prospective and interventional clinical study, was performed using the EPIONE™ device for liver ablations on 21 patients under general anesthesia to supplement the bench and preclinical animal testing and confirm the safety and performance of the device. The results of this study show that the EPIONE™ device is safe and effective for CT-guided percutaneous procedures for liver ablations under general anesthesia conditions with no adverse events reported for any of the subjects.

Conclusions

Compared to the predicate, the EPIONE device has the same intended use, indications for use within that of the predicate, patient anesthesia condition within that of the predicate, and equivalent technological characteristics. The differences between the EPIONE device and the predicate do not raise different questions of safety and effectiveness. The testing including bench testing, animal, and clinical testing demonstrated that the device should be as safe and effective in achieving its intended use as in the predicate. The EPIONE™ device is therefore substantially equivalent to the identified predicate device.