May 3, 2023

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

Re: K223758
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: March 31, 2023
Received: April 3, 2023

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223758

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 ablation procedures in the abdomen, performed by physicians trained for CT procedures and performed under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G. 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.

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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K223758

510(k) SUMMARY

Date prepared: 02, May 2023

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

Primary Predicate Device
EPIONE® (JAK, K211645), Quantum Surgical SAS

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

Note : This proposed new version for EPIONE, will be referred to as "EPIONE v1.0.2" to differentiate it from the original EPIONE predicate.

Device Description

The proposed Epione v1.0.2 is a modified version of the Epione predicate device as was cleared under 510(k) K211645. Aside from the modifications that are summarized further below, the Epione v1.0.2 is the same as the predicate as follows.

The EPIONE device v1.0.2 is a user controlled, stereotactic accessory device 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 with rigid straight instruments such as needles, and applicators (cryoprobes, electrodes, and antennas), used in CT-guided interventional procedures performed by physicians trained for CT procedures on organs and anatomical structures in the abdomen.

The EPIONE device v1.0.2 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 Short Navigation probe

The modifications include :

- expanding its ablation procedure indications to organs in the abdomen as compared to ablation procedures only on the liver in the Epione predicate,
- the addition of a new software functionalities to facilitate multi-needle planning that include configurable multiple needle array configurations for simultaneous needle group planning as compared to the planning of one needle at a time in a sequential manner in the Epione predicate,
- the addition of post-procedure imaging software tools to measure the post-procedure ablated zones as compared to only visual assessment in the Epione predicate, and
- the addition of an alternate shortened version of the navigation probe as compared to original longer version in the Epione predicate. This short navigation probe replaces the longer original navigation probe.

EPIONE v1.0.2 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 ablation procedures in the abdomen, performed by physicians trained for CT procedures and performed under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G.

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.

Comparison with the primary and secondary predicate devices

	EPIONE v1.0.2 Proposed device	EPIONE Primary Predicate device	MAXIO Secondary 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 ablation procedures in the abdomen, performed by physicians trained for CT procedures and performed under general anesthesia with rigid straight instruments such as needles and probes of diameters ranging from 11G to 19G.** 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 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 level**s 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 **general** anesthesia conditions	For use under **local and general** anesthesia conditions
Intra-interventional Planning	Physician defines trajectories 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.	Physician defines trajectory per an entry point and a target point on CT images.
Interventional instruments	Rigid straight interventional instruments such as needles, probes for biopsy, ablation and drainage from 11G to 19G	Rigid straight interventional instruments such as needles, probes for biopsy, ablation and drainage from 11G to 19G	Rigid straight interventional instruments such as needles, probes for biopsy, ablation and drainage from 11G to 21G.

	EPIONE v1.0.2 Proposed device	EPIONE Primary Predicate device	MAXIO Secondary Predicate device
Needle configuration and performance	• Needle selection amongst a list of predefined needles • Manufacturer defined performances (e.g. ablation zones) • User-defined performances (tools for assessment of ablation zones)	• Needle selection among a list of predefined needles • Manufacturer defined performances (e.g. ablation zones)	• Needle selection amongst a list of predefined needles • Manufacturer defined performances (e.g. ablation zones). • User-defined performances (tools for assessment of ablation zones).
Needle guidance	• Robotic arm with needle guide is positioned on the desired trajectories 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 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.	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 CT scan 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.	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 are also used to verify also per a laser cross-hairs that the relative locations of the CT scan 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 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

	EPIONE v1.0.2 Proposed device	EPIONE Primary Predicate device	MAXIO Secondary Predicate device
			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	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.	Register intra-interventional CT series with post procedure CT series to display planned target position on Post-procedure CT image. Also includes tools to segment ablated zone in post-ablation images, and to register pre and post ablation image, to perform a visual assessment of the ablation.

The comparisons between the EPIONE v1.0.2 and EPIONE and MAXIO predicates determined that:

- The general intended use is unchanged with the proposed modifications and is equivalent to that of the EPIONE and Maxio predicates.
- The extension of the anatomical/organ anatomy indication in the EPIONE v1.0.2 to include procedures on organs and structures in the abdominal area, as compared to procedures on the liver in the EPIONE predicate, is within the indications of the secondary Maxio predicate. This extension in indications was supported with clinical data showing equivalent performance to the Maxio predicate.
- The EPIONE v1.0.2 has equivalent technological characteristics to the predicates. The new software multi-needle and ablation assessment features and the new shorter Navigation Probe instrument include modified/improved engineering methods or specifications without impacting the overall technology, intended use, or indications for use. The added multi-needle and ablation software tools are also similarly provided in the Maxio predicate. These changes do not raise different questions of safety or effectiveness as compared to the predicates.

Summary of Non-Clinical Performance Data:

To establish substantial equivalence with predicates and to verify that the EPIONE v1.0.2 will perform safely and effectively per its intended use equivalently to the EPIONE predicate:

- The following in-vitro performance tests were repeated from the EPIONE predicate to verify that no software implementation errors were introduced:
    - Overall System Accuracy Tests,
    - Respiratory Monitoring Effectiveness Tests and
- The positional accuracy testing was re-performed as in the Epione predicate in accordance with the *ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems* to re-verify that the static positioning accuracy of the device when using the new shorter navigation probe was maintained as in the Epione predicate with the longer navigation probe.
- Usability Testing, in accordance to IEC 62366-1:2015 and the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* was re-performed similarly as the EPIONE predicate to demonstrate that the new multi-needle feature is safe and effective for the intended users, uses and use environments.

Additionally, Software design and verification and validation testing was completed similarly as in the Epione predicate to establish the device's safety and effectiveness including verifying the correct implementation of the various software changes in compliance to the FDA guidance "*Content of Premarket Submissions for Software Contained in Medical Devices",* the new draft guidance *"Content of Premarket Submissions for Device Software Functions",* 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"*.

Clinical study

This includes the interim data from an ongoing clinical in France. The main objective of this non-interventional study is to investigate the performance of EPIONE v1.0.2 as used for CT-guided procedures in different organs of the abdomen. The interim results of this study with the first 33 patients demonstrate the in-vivo equivalence in safety and effectiveness of the EPIONE v1.0.2 for procedures in the abdomen as compared to the predicates.

Conclusions

The EPIONE v1.0.2 was demonstrated to have the same overall intended use as the predicates with its expanded indication from its Epione predicate being within that of the Maxio predicate. The information supports that it has equivalent technological characteristics with differences with the predicates that do not raise different questions of safety and effectiveness. The testing includes bench testing, animal, and clinical testing demonstrating that the device should be as safe and effective in achieving its intended use as in the predicates. The EPIONE device v1.0.2 is therefore substantially equivalent to the predicates devices.