Eigen
℅ William Mandel
Director of Operations, Regulatory Affairs, and Quality Assurance
13300 Grass Valley Avenue, Suite A
GRASS VALLEY CA 95945

Re: K222222 October 12, 2023
Trade/Device Name: Artemis
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QTZ, GEH
Dated: September 28, 2023
Received: October 3, 2023

Dear William Mandel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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)*

K222222

Device Name
Artemis

Indications for Use *(Describe)*

Artemis along with the Needle Guide Attachment is used for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (US) images and the ability to fuse and register these images with those from other imaging modalities such as Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. The software also provides a virtual grid on the live ultrasound for performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management.

Artemis is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in active surveillance to keep track of previous procedures information and outcomes.

Artemis Cryo Treatment Planning module is an add on to the existing Artemis software that allows physicians to prepare for cryo treatment planning based on positive pathology cores obtained during Artemis guided biopsies and registration results with other imaging modalities such as MRI, CT. The module allows accurate placement of cryo probes on targets, 3D tracking, real-time feedback on extend of cryo ice formation. The technology provided by Artemis generates ice models based on the specifications provided by the cryo device manufacturers and displays the models on the live ultrasound to provide guidance to the users during the procedure.

The module also allows outlining or segmenting other organs that surround the prostate. Organs include bladder and urethra. □

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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leading innovation in medical imaging eigen

510(k) Summary K222222

Submitter's Name:	Eigen
Submitter's Address:	13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone:	530-274-1240
Submitter's Fax:	530-274-3536
Contact Name:	William Mandel
Date Summary was Prepared:	Feb 11, 2022
Trade or Proprietary Name:	Artemis
Common or Usual Name:	Medical Image Processing Workstation
Classification Name:	Primary - Radiological Image Processing for Ablation Therapy Planning and Evaluation, QTZ Secondary – Unit, Cryosurgical, Accessories, GEH Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number	Type
Artemis	K162474	Primary
ICEfx Cryoablation System	K181153	Reference

The design, function, and specifications of Artemis are similar to the identified legally marketed predicate devices. Similar to the devices from Eigen, LLC (K162474), ICEfx Cryoablation System (K181153), Artemis provides image-guided interventional planning and navigation for prostate procedures, the ability to view and capture live 2D ultrasound data to create reconstructed 3D ultrasound images/models and the ability to fuse and register these images with those acquired and imported from other modalities like Magnetic Resonance Imaging, X-ray Computed Tomography, and Ultrasound. Artemis also performs other viewing and image-processing functions such as image registration, multi-planar reformats and includes tools to segment, measure and annotate images. Similar to predicate devices, the subject device can import data from other DICOM based imaging devices and also output selected image views, processed data and user-defined reports. Similar to ICEfx Cryoablation System (K181153) listed predicate device, Artemis provides Navigation of cryo-needles and visual growth of ice-balls.

The ICEfx Cryoablation System (K181153) utilizes its own cryo-needles while Artemis utilizes a

mechanical semi-robotic arm with encoders to navigate third party cryo-needles.

This difference in navigation and tracking technique does not significantly affect the use of the device, nor does it raise new or additional safety risks. This difference between Artemis and ICEfx Cryoablation System (K181153) devices does not impact device safety or effectiveness.

Artemis and 3D-Imaging Workstation (K162474) utilize the identical mechanical navigation and tracking mechanism.

The current Artemis for this 510(k) and the previous Artemis (K162474) also share common software source code for basic system functionality such as multi-modality image viewing, segmentation, registration, navigation, annotation, reporting and DICOM functionality.

Description of the Device and Summary of the Technological Characteristics

Artemis is designed to display the 2-D live video received from commercially available ultrasound machines and use this 2-D video to reconstruct a 3-D ultrasound image. The system has been designed to work with the clinicians' existing ultrasound machine, probe, commercially available biopsy needle guide, needle gun combination, and cryoablation systems. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement, reporting and 3-D image registration.

Artemis is comprised of a mechanical assembly that holds the ultrasound probe and tracks probe position. The mechanical tracker is connected to a PC-based workstation containing a video digitizing card and running the image processing software. Control of the ultrasound probe and ultrasound system is done manually by the physician, just as it would be in the absence of Artemis. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, the workstation is able to reconstruct and display a 3-D image and 3-D rendered surface model of the prostate.

The reconstructed 3-D image can be further processed to perform various

measurements including volume estimation, and can be examined for abnormalities by the physician. Patient information, notes, and images may be stored for future retrieval. Locations for biopsies may be selected by the physician, displayed on the 3-D image and 3-D rendered surface model, and stored. Previously stored 3-D models may be recalled and a stored 3-D model may be aligned or registered to the current 3-D model of the prostate. This is especially useful for patients under active surveillance.

The physician may attach a commercially available biopsy needle guide compatible to the ultrasound probe and use the probe and needle to perform tissue biopsy and or cryoablation. Whenever the ultrasound machine is turned on by the physician, the live 2-D ultrasound image is displayed on the screen of Artemis during the procedure. As the ultrasound probe with attached needle guide is maneuvered by the physician, the position and orientation of the probe with respect to the organ is tracked. Artemis is able to add, display and edit loaded plans for the procedure as well as provide the probe position and needle trajectory relative to the 3-D image and 3-D rendered surface model of the prostate.

In addition to standard transrectal needle guidance procedures, Artemis also supports transperineal needle guidance by mounting a Needle Guide Attachment (NGA). A commercially available needle guide compatible with the NGA is used. This NGA will be used for both biopsy and cryo needles. The NGA provides additional data to track the needle direction angle. When using transperineal mode, the procedure planning, segmentation, registration and navigation are performed in the same way as the standard transrectal procedure. The only difference lies in how the needle guide needs to be moved to target the different planned locations. For the transrectal procedure, the needle guide is always attached to the probe. Therefore moving the probe moves the needle guide. In transperineal needle guidance procedures the needle is not attached to the probe. Therefore the NGA needs to be moved to move the needle guide. Artemis highlights the closed target to the current needle guide position.

Artemis offers the physician additional 3-D information for assessing prostate abnormalities, planning and implementing biopsy procedures. The additional image processing features are generated with minimal changes to previous Ultrasound probe based procedures,

and the physician always has access to the live 2-D ultrasound image during prostate assessment or biopsy procedure. The device also provides automated reports with information and pictures from the procedure.

Intended Use

Artemis along with the Needle Guide Attachment is used for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (US) images and the ability to fuse and register these images with those from other imaging modalities such as Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. The software also provides a virtual grid on the live ultrasound for performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management.

Artemis is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in active surveillance to keep track of previous procedures information and outcomes.

Artemis Cryo Treatment Planning module is an add on to the existing Artemis software that allows physicians to prepare for cryo treatment planning based on positive pathology cores obtained during Artemis guided biopsies and registration results with other imaging modalities such as MRI, CT. The module allows accurate placement of cryo probes on targets, 3D tracking, real-time feedback on extend of cryo ice formation. The technology

provided by Artemis generates ice models based on the specifications provided by the cryo device manufacturers and displays the models on the live ultrasound to provide guidance to the users during the procedure.

The module also allows outlining or segmenting other organs that surround the prostate. Organs include bladder, and urethra.

Substantial Equivalence

Following is a comparison of technological characteristics between Artemis and predicate devices:

Product	Submitted Device Eigen Artemis	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: ICEfx Cryoablation System (K181153)
Intended Use	Artemis along with the Needle Guide Attachment is used for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (US) images and the ability to fuse and register these images with those from other imaging modalities such as Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. The software also provides a virtual grid on the live ultrasound for performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management. Artemis is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in	Artemis along with the Needle Guide Attachment is used for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (US) images and the ability to fuse and register these images with those from other imaging modalities such as Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. The software also provides a virtual grid on the live ultrasound for performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management. Artemis is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in	The ICEfx Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology and urology. This System is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures. The ICEfx Cryoablation System has the following specific indications: • Urology Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH) • Oncology Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention • Dermatology Ablation or freezing of skin cancers and other cutaneous disorders; Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin

	active surveillance to keep track of previous procedures information and outcomes. Artemis Cryo Treatment Planning module is an add on to the existing Artemis software that allows physicians to prepare for cryo treatment planning based on positive pathology cores obtained during Artemis guided biopsies and registration results with other imaging modalities such as MRI, CT. The module allows accurate placement of cryo probes on targets, 3D tracking, real-time feedback on extend of cryo ice formation. The technology provided by Artemis generates ice models based on the specifications provided by the cryo device manufacturers and displays the models on the live ultrasound to provide guidance to the users during the procedure. The module also allows outlining or segmenting other organs that surround the prostate. Organs include bladder, and urethra.	active surveillance to keep track of previous procedures information and outcomes. -	• Gynecology Ablation of malignant neoplasia or benign dysplasia of the female genitalia • General surgery Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas • ENT Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth • Thoracic surgery (with the exception of cardiac tissue) • Proctology Ablation of benign or malignant growths of the anus or rectum
Product	Submitted Device Eigen Artemis	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: ICEfx Cryoablation System (K181153)
Product Code	QTZ, GEH	LLZ	GEH
Class	II	II	II
Target Anatomy	Prostate	Prostate	Prostate
Anatomy Access	Transrectal & Transperineal	Transrectal & Transperineal	Transperineal
Software			
Windows OS	Yes	Yes	Yes
Medical Imaging Software	Yes	Yes	Yes
Image Display			

Multi-Modality Support	Yes	Yes	Yes
General Image 2D/3D Review	Yes	Yes	Yes
3D Rendering View	Yes	Yes	Yes
Live 2D Ultrasound	Yes	Yes	Yes
Image Processing			
Gland Segmentation	Yes	Yes	Yes
Image Registration	Yes	Yes	unknown
Rigid Registration	Yes	Yes	unknown
Elastic Registration	Yes	Yes	unknown
Multi-Planar Reformation	Yes	Yes	unknown
Connectivity			
DICOM Import/Export	Yes	Yes	unknown
Ultrasound Video	Yes	Yes	unknown
Review Tools			
Stand Image Viewing Tools	Yes	Yes	unknown
Measurement Tools	Yes	Yes	unknown
Product	Submitted Device Eigen Artemis	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: ICEfx Cryoablation System (K181153)
Annotation Tools	Yes	Yes	Yes
Segmentation Tools	Yes	Yes	unknown
Reporting Tools	Yes	Yes	Yes
Video Capture	Yes	Yes	unknown
Image Overlays	Yes	Yes	Yes
Planning & Navigation			
Import Prior Plans	Yes	Yes	unknown

Import/Add targets	Yes	Yes	unknown
Plan/Marks Locations	Yes	Yes	Yes
Navigation Type	Mechanical	Mechanical	CT

The new device and predicate devices are substantially equivalent in the areas of technological characteristics such as basic design, features, energy source, method of operation, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Safety and Effectiveness

Artemis labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via Artemis Risk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via the product (software and hardware) development process, verification and validation testing.

Nonclinical Testing and Performance Information

Nonclinical and performance testing has been performed by designated individuals as required by Eigen's quality procedures. Verification & Validation Test Plans were designed to evaluate all input functions, output functions, and actions performed by Artemis in each operational mode. Artemis has been assessed and tested at the manufacturer's facility and has passed all in-house testing criteria including validating design, function and specifications. Measurement validation using, phantoms, clinical CT, and MRI images were used to show that Artemis preforms as well as or better than the predicate devices and furthermore shows that Artemis was safe and effective. Nonclinical and performance testing results are provided in the 510(k) and demonstrate that the predetermined acceptance criteria are met. The Artemis has been designed to comply with the applicable standards:

Emissions:

IEC/EN 60601-1-2:2007/AC:2010, EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010, IEC 61000-3-2:2005+A1:2009 +A2: 2009, EN 61000-3-2:2006+A1:2009 +A2: 2009, IEC 61000-3-3:2008, EN 61000-3-3:2008
IEC 60601-1-2:2014 - - Medical electrical equipment

Immunity:

IEC/EN 60601-1-2:2007/AC:2010, IEC 61000-4-2:2008, EN 61000-4-2:2009, IEC 61000-4-3:2006+A1:2008 +A2:2010, EN 61000-4-3:2006+A1:2008 +A2:2010, IEC 61000-4-4: 2004+A1:2010, EN 61000-4-4:2004+A1:2010, IEC 61000-45:2005, EN61000-4-5:2006, IEC61000-4-6:2004/A2:2006, EN61000-46:2009, IEC 61000-4-8:2009,EN61000-4-8:2010,IEC61000-4-11:2004,, EN61000-4-11:2004
EC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1
(2012) or IEC 60601-1: 2012
IEC 60601-1-6:2010, AMD1:2013

Risk and Usability

- EN/ISO 14971:2012

- IEC 62366:2007

- IEC 60601-1-6:2010

Conclusion

The 510(k) Pre-Market Notification for Artemis contains adequate information, data, and nonclinical test results to enable FDA – CDRH to determine substantial equivalence to the predicate devices. Eigen has determined that its device, Artemis, is substantially equivalent to the identified predicate devices listed above. A comparison with the legally marketed predicate devices indicates that the device is substantially equivalent to the predicate device, and that it does not raise any new safety or efficacy concerns. The results of comparing the intended use, function, technological characteristics, mode of operation, and specifications of Artemis with those of the two predicate devices demonstrate that Artemis is substantially equivalent to the primary predicate device.