



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Eigen
% Mr. William Mandel
Director Of Operations, Regulatory Affairs and Quality Assurance
13366 Grass Valley Avenue
GRASS VALLEY CA 95945

October 21, 2016

Re: K162474
Trade/Device Name: Artemis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 11, 2016
Received: September 6, 2016

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned over a large, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162474

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.

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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510(k) Summary

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: Aug 11, 2016
 Trade or Proprietary Name: Artemis
 Common or Usual Name: Medical Image Processing Workstation
 Classification Name: System, Image Processing, Radiological, LLZ
 Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
3-D Imaging Workstation	K081093
UroNav (Version 2.0)	K153073

The design, function, and specifications of Artemis are similar to the identified legally marketed predicate devices. Similar to the devices from Eigen, LLC (K081093), Invivo UroNav (K153073), 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. Similar to all of the above listed predicate devices, 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. Each of the devices can import data from other DICOM based imaging devices and also output selected image views, processed data and user-defined reports.

The main difference between Artemis and the UroNav (K153073) device is the method used for procedure navigation and tracking.

The UroNav system utilizes an Electromagnetic Measurement System (EMMS) for procedure navigation and tracking while Artemis utilizes a mechanical semi-robotic arm with encoders to

determine the location of the ultrasound probe.

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 UroNav devices does not impact device safety or effectiveness.

Artemis and 3D-Imaging Workstation (K121498) utilize the identical mechanical navigation and tracking mechanism.

Artemis and 3D-Imaging Workstation (K121498) 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, TRUS probe, commercially available needle guide, and needle gun combination. 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 TRUS probe and use the probe and biopsy needle to perform tissue biopsy. 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 biopsy. As the TRUS 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 biopsy 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. 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 TRUS 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.

Substantial Equivalence

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

Product	Submitted Device Eigen Artemis	Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Predicate Device: Invivo UroNav (Version 2.0) K153073
Intended Use	<p>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.</p> <p>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.</p> <p>-</p>	<p>The 3-D Imaging Workstation is intended to be used by physicians in the clinic or hospital for 2-D and 3-D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3-D image registration.</p>	<p>UroNav is a stereotaxic accessory 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 Magnetic Resonance (MR), Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire, gridplate 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. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 2D/3D image registration.</p> <p>UroNav 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.</p>

Product	Submitted Device Eigen Artemis	Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Predicate Device: Invivo UroNav (Version 2.0) K153073
Product Code	LLZ	LLZ	LLZ
Class	II	II	II
Target Anatomy	Prostate	Prostate	Prostate
Anatomy Access	Transrectal & Transperineal	Transrectal	Transrectal & 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	Yes
Rigid Registration	Yes	Yes	Yes
Elastic Registration	Yes	Yes	Yes
Multi-Planar Reformation	Yes	Yes	Yes
Connectivity			
DICOM Import/Export	Yes	Yes	Yes
Ultrasound Video	Yes	Yes	Yes
Review Tools			
Stand Image Viewing Tools	Yes	Yes	Yes
Measurement Tools	Yes	Yes	Yes
Annotation Tools	Yes	Yes	Yes
Segmentation Tools	Yes	Yes	Yes
Reporting Tools	Yes	Yes	Yes
Video Capture	Yes	Yes	Yes
Image Overlays	Yes	Yes	Yes
Planning & Navigation			
Import Prior Plans	Yes	Yes	Yes
Import/Add targets	Yes	Yes	Yes

Product	Submitted Device Eigen Artemis	Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Predicate Device: Invivo UroNav (Version 2.0) K153073
Plan/Marks Locations	Yes	Yes	Yes
Navigation Type	Mechanical	Mechanical	Electromagnetic

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 performs as well as or better than the other 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

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

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 it is substantially equivalent to this 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 existing products in the market today.