DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 16, 2015

Invivo Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K153073
Trade/Device Name: Uronav (Version 2.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 21 2015
Received: October 22, 2015

Dear Mr. Job:

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153073

Device Name
UroNav (Version 2.0)

Indications for Use *(Describe)*

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.

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.

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

Submitted by:	Invivo Corporation 3545 SW 47th Avenue Gainesville, FL 32608
Establishment Name:	Invivo Corporation
Establishment Registration Number:	1056069
Contact Person:	Kenneth Revennaugh Director, Quality and Regulatory Invivo Corporation 3545 SW 47th Avenue Gainesville, FL 32608 Phone: (352) 384-8590 Email: kenrevennaugh@philips.com
Date Prepared:	October 5, 2015
Trade Name:	UroNav (Version 2.0)
Common Name:	Medical Image Processing Workstation
Classification Name:	System, Image Processing, Radiological
Classification Regulation Number:	892.2050
Classification:	Class II
Classification Panel:	Radiology
Product Code:	LLZ

Device Description

UroNav is a medical image processing workstation that provides image-guided intervention and diagnostic information, which guides interventional instrumentation to targets that have been defined by the physician. The target can be indicated either pre-procedurally or intra-procedurally using images or relative to an indicated position on the patient. As a diagnostic system, it combines pre-procedural and intra-procedural imaging to assist in locating areas of interest detected on one set of images on the other. The system provides fusion between Ultrasound (US) and different imaging modalities such as Magnetic Resonance Imaging (MR), Computed Tomography (CT), etc. When used as a navigation aid, it also transforms two and three-dimensional patient images (scan sets) into dynamic representations on which a medical instrument can be navigated. The system performs spatial mapping from one image space to another image space or from image space to physical space ("registration") allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive interventional procedures. Images used by UroNav can include archived image data from a CD, PACS, etc., and live images from an ultrasound system.

The UroNav system consists of an Electromagnetic Measurement System (EMMS) (including a Field Generator, System Control Unit and System Interface Unit(s)), a System Unit (including a CPU/monitor, medical-grade power supply and mobile cart), Field Generator stand, UroNav software and various instrumentation devices. The UroNav System Unit and the UroNav software utilize the keyboard, mouse and visual display to interact with the image data from a connected Ultrasound System. This interaction includes the selection of targets and associated navigation on the UroNav monitor. Targeted use areas for UroNav include hospital operating rooms, outpatient surgery centers, ultrasound suites, and procedure rooms.

UroNav is designed to display the 2D live video received from commercially available ultrasound machines and use this 2D video to reconstruct a 3D ultrasound image. The system has been designed to work with the clinicians' existing ultrasound machine, transrectal ultrasound (TRUS) probe, commercially available needle guides and needle gun combinations. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3D image registration. UroNav utilizes an electromagnetic measurement system (EMMS) for identifying and tracking the location of the TRUS probe (and associated needle guides, instruments, etc.) relative to the 2D and 3D images. The EMMS Field Generator is positioned near the patient and provides an electromagnetic (EM) field for detection by a proprietary electromagnetic (EM) Sensor, which is attached to the ultrasound probe and tracks probe position while the physician performs a normal ultrasound imaging procedure of the subject prostate. The Field Generator and EM Sensor are connected to the UroNav

System Control Unit and the PC running the UroNav software. Control of the ultrasound probe and ultrasound system is done manually by the physician, just as it would be in the absence of UroNav. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, UroNav is able to reconstruct and display a 3D image and 3D rendered surface model of the prostate.

The reconstructed 3D 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, needles, markers, and other devices may be selected by the physician, displayed in the 3D image and 3D rendered surface model, and stored. Previously created 3D models may be recalled and may be aligned or registered to the current live display of the prostate. The 3D model used for co-registration may be based on another series of ultrasound images or DICOM images.

The physician may also attach a commercially available biopsy needle guide 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 2D ultrasound image is displayed on the UroNav display during the biopsy. As the TRUS probe with attached needle guide is maneuvered by the physician, the position and orientation of the probe is tracked. UroNav is able to add, display and edit plans for target locations (e.g., biopsy sites) as well as an estimate of the probe position and needle trajectory relative to the 3D image and 3D rendered surface model of the prostate and the planned target locations. UroNav offers the physician additional 3D 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 2D ultrasound image during prostate assessment or biopsy procedure.

In addition to standard transrectal procedures, UroNav also supports transperineal access and commercially available gridplates normally used for performing such procedures. When using transperineal mode, the UroNav EM Sensors are attached to both the TRUS probe and the transperineal gridplate within a mechanical stepper assembly. Procedure planning, segmentation, registration and navigation are performed the same as the standard transrectal procedure except that a computer rendering of the transperineal gridplate is displayed on the UroNav display. UroNav provides an indication of the gridplate coordinates that correspond to the identified target location.

Intended Use

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.

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.

Predicate Device Information & Comparison

Predicate Devices Name	Predicate 510(k) Submission References
3-D Imaging Workstation	K081093 (Primary)
BioJet	K122329 (Reference)
PercuNav	K121498 (Reference)

The design, function, and specifications of UroNav are similar to the identified legally marketed predicate devices. Similar to the devices from Eigen, LLC (K081093), Jet Soft, SRL (K122329) and Philips Healthcare (K121498), UroNav 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 DICOM-based imaging devices. Similar to all of the above listed predicate devices, UroNav 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 also output selected image views, processed data and user-defined reports.

The main difference between UroNav and the Eigen 3-D Imaging Workstation (K081093) and BioJet (K122329) devices is the method used for procedure navigation and tracking. The UroNav system utilizes an Electromagnetic Measurement System (EMMS) for procedure navigation and tracking while the 3-D Imaging Workstation and BioJet devices utilize a mechanical encoding system 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 UroNav and the Eigen 3-D Imaging Workstation and BioJet devices does not impact device safety or effectiveness.

UroNav and PercuNav (K121498) utilize the identical commercially available Electromagnetic Measurement System (EMMS) for procedure navigation and tracking. UroNav and PercuNav also share common software source code for basic system functionality such as multi-modality image viewing, segmentation, registration, EM navigation, annotation and DICOM functionality.

The differences between UroNav and PercuNav (K121498) include a limited number of indications, options and features of the predicate device, which are not included in the submitted device. While both devices support interventional and diagnostic procedures, the UroNav system does not include support for all of the anatomic locations indicated for PercuNav (e.g., liver, lung, pancreas, etc.). The absence of these anatomic locations does not significantly affect the use of the device, nor does it raise new or additional safety risks. This difference between UroNav and the PercuNav device does not impact device safety or effectiveness.

Other differences between UroNav and the identified predicate devices include minor user interface variations such as GUI design, screen colors and image viewing layouts. These differences are cosmetic in nature do not significantly affect the use of the device, nor do they raise new or additional safety risks. These differences between UroNav and the legally marketed predicate devices do not impact device safety or effectiveness.

Safety and Effectiveness

The UroNav 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 Invivo's 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 Invivo Corporation's quality procedures. Verification & Validation Test Plans were designed to evaluate all input functions, output functions, and actions performed by UroNav in each operational mode. UroNav has been assessed and tested at the manufacturer's facility and has passed all in-house testing criteria including validating design, function and specifications. Nonclinical and performance testing results are provided in the 510(k) and demonstrate that the predetermined acceptance criteria are met. The UroNav has been designed to comply with the applicable standards:

- IEC 60601-1:2005
- IEC 60601-1-2:2007
- EN/ISO 14971:2007
- IEC 62366:2007
- IEC 60601-1-6:2010

Technological Characteristics

UroNav is a diagnostic and interventional accessory that is comprised of a mobile computer workstation, a commercially-available navigation device and software with functions that are commonly found in various medical imaging applications. It provides convenient options for visualizing diagnostic and interventional information in support of routine clinical procedures of the prostate gland. The device does not directly contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the UroNav system but by Radiologists, Urologists, Clinicians and referring Physicians.

A physician, providing ample opportunity for competent human intervention interprets the images and information being displayed and maintains control of the clinical procedure at all times.

The UroNav utilizes the same technological characteristics as the predicate devices. Both:

- are PC based software applications that provide 2D and 3D medical image acquisition including ultrasound video image acquisition arid visualization of the prostate gland
- use Windows operating systems
- allow co-registration of live ultrasound images to previously created 3-0 image sets based on previously collected live ultrasound image sets or DICOM images sets
- include image enhancements such as contrast and brightness, zoom and pan capabilities

- provide patient and clinical data management features
- deal with live ultrasound images received from commercially available imaging devices
- use graphic overlays to define segmentations
- calibrate ultrasound video images
- create a report
- allow for image measurements such as volume, length, and angle measurements
- allow multi-planar reformatting
- allow manual planning of instrument positioning including biopsy needle placement and planning
- allow the user to plan and mark the reached positions of the biopsies and instruments
- do not steer or in any way control the positioning of the instruments used or of any treatment process what so ever
- are only intended for use on the prostate gland

Following is the comparison of technological characteristics between UroNav and predicate devices:

Product	**Submitted Device: Invivo UroNav (Version 2.0)**	**Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093**	**Reference Predicate Device: Jet Soft SRL BioJet K122329**	**Reference Predicate Device: Philips Healthcare PercuNav K121498**
Intended Use	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	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.	The BioJet software is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurements, and 3-D registration.	PercuNav is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Rotational Fluoroscopy, Endoscopy, and other imaging systems. CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, such as CT with MR, MR with ultrasound, etc. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor

Product	Submitted Device: Invivo UroNav (Version 2.0)	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: Jet Soft SRL BioJet K122329	Reference Predicate Device: Philips Healthcare PercuNav K121498
	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, multiplanar reconstruction, segmentation, image measurements and 2D/3D image registration. 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.			screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account patient movement. This is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device also supports an image free mode in which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another. Example procedures include, but are not limited to: • Image fusion for diagnostic clinical examinations and procedures • Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, etc.) • Soft tissue ablation (liver, kidney, breast, pancreas, lung, etc.) • Bone ablation • Bone biopsies • Nerve Blocks & Pain Management • Drainage placements

Product	Submitted Device: Invivo UroNav (Version 2.0)	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: Jet Soft SRL BioJet K122329	Reference Predicate Device: Philips Healthcare PercuNav K121498
				• Hydrodissections • Bladder Stimulation • Fiducial placements • Tumor resections • Sinus procedures • Intranasal procedures • Transphenoidal procedures
Decision Date	Pending	05/01/2008	08/16/2012	12/14/2012
Product Code	LLZ	LLZ	LLZ	JAK
Class	II	II	II	II
Target Anatomy	Prostate	Prostate	Prostate	Multiple
Anatomy Access	Transrectal & Transperineal	Transrectal & Transperineal	Transrectal & Transperineal	Multiple (including Transrectal)
Software				
Windows O.S.	Yes	Yes	Yes	Yes
Medical Imaging Software	Yes	Yes	Yes	Yes
Image Display				
Multi-Modality Support	Yes	Yes	Yes	Yes
General Image 2D/3D Review	Yes	Yes	Yes	Yes
3D Rendering View	Yes	Yes	Yes	Yes
Live 2D Ultrasound	Yes	Yes	Yes	Yes
Image Processing				
Gland Segmentation	Yes	Yes	Yes	Yes
Image Registration	Yes	Yes	Yes	Yes
Rigid Registration	Yes	Yes	Yes	Yes
Elastic Registration	Yes	Yes	No	Yes
Multi-Planar Reformatting (MPR)	Yes	Yes	Yes	Yes
Connectivity				
DICOM Import/Export	Yes	Yes	Yes	Yes
Ultrasound Video	Yes	Yes	Yes	Yes
Review Tools				
Standard Image Viewing Tools	Yes	Yes	Yes	Yes

Product	Submitted Device: Invivo UroNav (Version 2.0)	Primary Predicate Device: Eigen, LLC 3-D Imaging Workstation K081093	Reference Predicate Device: Jet Soft SRL BioJet K122329	Reference Predicate Device: Philips Healthcare PercuNav K121498
Measurement Tools	Yes	Yes	Yes	Yes
Annotation Tools	Yes	Yes	Yes	Yes
Segmentation Tools	Yes	Yes	Yes	Yes
Reporting Tools	Yes	Yes	Yes	Yes
Video Capture	Yes	Yes	No	Yes
Image Overlays	Yes	Yes	Yes	Yes
Planning & Navigation				
Import Prior Plans	Yes	Yes	Yes	Yes
Import/Add Targets	Yes	Yes	Yes	Yes
Plan/Mark Locations	Yes	Yes	Yes	Yes
Navigation Type	Electromagnetic	Mechanical	Mechanical	Electromagnetic

The new device and predicate devices are substantially equivalent in the areas of technological characteristics such as basic design, features, 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.

Conclusion

The 510(k) Pre-Market Notification for UroNav contains adequate information, data, and nonclinical test results to enable FDA – CDRH to determine substantial equivalence to the predicate devices. Invivo has determined that its device, UroNav, 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. Nonclinical tests demonstrate that the device is safe, effective, and is substantially equivalent to the predicate devices.

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