



Invivo Corporation
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL, MN 55114

December 27, 2019

Re: K193403
Trade/Device Name: UroNav System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 4, 2019
Received: December 6, 2019

Dear Prithul Bom:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K193403

Device Name

UroNav System

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 (U/S) images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic Resonance (MR). It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire, grid plate 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, 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.

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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6. 510(k) Summary

K193403

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: October 9, 2019

Manufacturer: Invivo Corporation
3545 SW 47th Ave
Gainesville, FL 32608

Primary Contact Person: Kym Rupp
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Device Name: UroNav System

Classification:	Classification Name:	Picture Archiving and Communications System
	Classification Regulation:	21CFR §892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	LLZ (system, image processing, radiological)
	Trade Name:	UroNav (Version 3.0)
Predicate Device:	Manufacturer:	Invivo Corporation 3545 SW 47th Ave Gainesville, FL 32608
	510(k) Clearance:	K182561 (October 19, 2018)
	Classification Regulation:	21 CFR, Part 892.2050

Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
Device Class: Class II
Product Code: LLZ (system, image processing, radiological)

**Device
description:**

UroNav System is a medical image processing system 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). 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.

The UroNav System 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 System**. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, **UroNav System** 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 System** 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 System** 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 System** 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 System** display. **UroNav System** provides an indication of the gridplate coordinates that correspond to the identified target location.

Indications for 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). 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.

Fundamental Scientific Technology:

The design, function, and specifications of **UroNav System** are similar to the identified legally marketed predicate devices. Similar to UroNav (Version 3.0 – K182561). **UroNav System** 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 the predicate device, the **UroNav System** 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.

UroNav System and the legally marketed predicate device, UroNav (Version 3.0) (K182561) utilize the identical commercially available Electromagnetic Measurement System (EMMS) for procedure navigation

and tracking. **UroNav System** and the legally marketed predicate device, UroNav (Version 3.0) also share common software source code for basic system functionality such as multi-modality image viewing, segmentation, registration, EM navigation, and annotation and DICOM functionality. Both **UroNav System** and legally marketed predicate device, UroNav (Version 3.0) can also be enabled as a software option on compatible ultrasound machines.

UroNav System and legally marketed predicate device, UroNav (Version 3.0) (K182561) utilize the identical commercially available Electromagnetic Measurement System (EMMS) for procedure navigation and tracking. **UroNav System** and legally marketed predicate device UroNav (Version 3.0) also share common software source code for basic system functionality such as multi-modality image viewing, segmentation, registration, EM navigation, and annotation and DICOM functionality.

The differences between **UroNav System** and legally marketed predicate device UroNav, (Version 3.0) is that **UroNav System** is a configurable device that has defined minimum computer requirements allowing deployment of the UroNav Software on to any system that meets the minimum computer requirements.

Based on the information provided above, the **UroNav System** is considered substantially equivalent to the primary currently marketed and predicate device (K182561, October 19, 2018) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

The **UroNav System** complies with the following international and FDA-recognized consensus standards:

- International and FDA-recognized consensus standards:
 - IEC 60601-1
 - IEC 62304
 - IEC 62366
 - ISO 14971

Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results.

Non Clinical verification and or validation test results demonstrate that the **UroNav System**:

- Complies with the aforementioned international and FDA-recognized consensus standards
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the **UroNav System** is substantially equivalent to the primary currently marketed and predicate device (K182561, October 19, 2018) in terms of safety and effectiveness.

**Summary of
Clinical Data:**

The **UroNav System** did not require clinical study since substantial equivalence to the primary currently marketed and predicate device was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

**Substantial
Equivalence
Conclusion:**

The **UroNav System** is substantially equivalent to the primary currently marketed and predicate device (K182561, October 19, 2018) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304, IEC 62366 and ISO 14971. The results of these tests demonstrate that **UroNav System** met the acceptance criteria and is adequate for this intended use.