UC-Care Ltd.
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th Street NW
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January 16, 2018

Re: K173054
Trade/Device Name: Navigo Workstation Version 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 19, 2017
Received: December 19, 2017

Dear Dr. Smith:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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 on last page

510(k) Number *(if known)*
K173054

Device Name

Navigo Workstation Version 2.0.

Indications for Use *(Describe)*

The UC-Care Navigo Workstation is an adjunctive tool for ultrasound guided procedures and 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. The Navigo Workstation offers the ability to fuse DICOM originated information (e.g. MRI, CT) with the ultrasound images and thus superimposes information from one modality onto the other.
It also provides the ability to display a simulated image of a tracked insertion tool such as a needle, guide wire, catheter, 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. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurement and 3-D image registration, as well as storage and future retrieval of this information.

Navigo 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

UC-Care Ltd.'s Navigo Workstation Version 2.0

Submitter

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Contact Person: Hadas Sheynise

Date Prepared: 29 September 2017

Name of Device: Navigo Workstation Version 2.0

Common or Usual Name: Navigo Workstation Version 2.0

Classification Name: Picture archiving and communications system

Regulatory Class: II

Regulation Number: 21 CFR 892.2050

Product Code: LLZ

Predicate Devices

UC-Care Ltd.'s Navigo Workstation K160934

InVivo Corporation's Uronav (Version 2.0) K153073

Device Description

The Navigo Workstation Version 2.0 is an adjunctive tool in the management of prostate diagnostic and interventional procedures. The Navigo Workstation Version 2.0 allows prostate needle tracking, recording, and management solution. The Navigo Workstation Version 2.0 is designed to assist the physician in performing prostate diagnostic and interventional procedures by providing regional orientation information, displaying a 3D model with real-time tracking and recording of the needle location. The Navigo Workstation Version 2.0 offers the ability to fuse DICOM originated information (e.g. MRI, CT) with the ultrasound images and thus superimposes information from one modality onto the other. The

device includes means to compensate for patient body and prostate motion at any time during the procedure.

The Navigo Workstation Version 2.0 is designed to work with standard trans-rectal / trans-perineal ultrasound systems and biopsy setup without changing or interfering with the physician's existing workflow. The Navigo Workstation Version 2.0 connects to the video output of the ultrasound system and by tracking the ultrasound probe's position, the recorded 2D ultrasound images are transferred to the Navigo Workstation Version 2.0 for viewing and creation of a 3D model. As with any other procedure, the US probe is used together with a standard disposable cover sheath supplied by the user.

Two dimensional (2D) images and the 3D model of the prostate are displayed on the Navigo Workstation Version 2.0's screen. The Navigo Workstation Version 2.0 is equipped with tools to manipulate (rotate, pan, zoom) the model, and to archive and retrieve the information for further use.

The tracking and recording enables display of an accurate 3D model of the prostate and to record needle locations on the model. Pathology diagnosis results may be updated on the 3D model and a color display representation provides a visual display of the pathology results.

The Navigo Workstation Version 2.0 supports the display of ROIs on the 3D model and displays visual indication when the needle trajectory intersects with an ROI. An ROI (Region Of Interest) is defined by the physician by segmenting a portion of the prostate on a 2D image and displaying its location on the 3D model, thereby defining a portion of the prostate as a target to direct a needle within. The 2D images for segmentation of the ROI can be either a frozen Ultrasound image or a DICOM compliant image from another imaging study completed prior to the Ultrasound procedure (e.g. MR,CT).The ROIs are clearly numbered and labeled by a letter symbolizing its origin (Ultrasound or DICOM). On each image, more than one ROI may be defined (segmented).

The live 2D ultrasound image is superimposed in real-time with the 2D ROI boundaries thus allowing the physician to see the real-time advancement of the needle on the live ultrasound image with reference to ROI boundaries. The 3D model is displayed on a separate window alongside the ultrasound's live continuous images display, allowing prostate 3D orientation.

Regardless of the type of ultrasound probe used for the procedure (side-fire or end-fire) a cannula for a needle is built within the outer shell of the probe and therefore a needle can be inserted through the designated cannula. The designated cannula defines the needle path along its trajectory. The needle trajectory is displayed on the 3D model representing the potential needle route to allow the physician to direct the needle in real time into the target. When the projected path intersects with an ROI, the color of the ROI will change indicating the needle can be directed inside the ROI if the physician ensures that the needle is inserted deep enough. In trans-perineal procedures the grid-plate sensor is placed on the grid base via a fixator; the sensor tracks the grid location during the procedure and enables the Navigo Workstation Version 2.0 to present in real time the optional trajectories locations. During the procedure, the physician may change some of the parameters on the US system or perform

different actions that require the Navigo Workstation Version 2.0 to adjust. A physician may wish to freeze an image and perform measurements, label the image and save it to the report, switch between transversal and longitudinal view, or change the view of the ultrasound image. The Navigo Workstation Version 2.0 is equipped with image state algorithms to automatically detect the change in parameters and adjust itself to the new parameters. For example, if the physician freezes the US image, the Navigo Workstation Version 2.0 will automatically present additional menu option for a frozen image like measurements tools and labeling. The image state algorithm was developed to support generic ultrasound parameters and is specifically tested for each new ultrasound system model the Navigo Workstation Version 2.0 is required to support. In case of auto-detection failure, the user is informed and asked to confirm or manually change the detected parameters In order to continue.

In off-line mode, the Navigo Workstation Version 2.0 software further enables the physician to analyze previous procedures using the prostate model, update the 3D model if necessary, update the recorded biopsies' locations, generate reports, and provides a DICOM (MRI/CT) interface for ROI definition, 3D model display, and data communication.

Intended Use / Indications for Use

The UC-Care Navigo Workstation is an adjunctive tool for ultrasound guided procedures and 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. The Navigo Workstation offers the ability to fuse DICOM originated information (e.g. MRI, CT) with the ultrasound images and thus superimposes information from one modality onto the other.

It also provides the ability to display a simulated image of a tracked insertion tool such as a needle, guide wire, catheter, 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. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurement and 3-D image registration, as well as storage and future retrieval of this information.

Navigo 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.

Summary of Technological Characteristics

The subject NaviGo™ Workstation Version 2.0 and the primary predicate, the NaviGo™ Workstation have the same general intended use, namely visualization of the prostate during an ultrasound procedure. The indications for use language has been updated for consistency with the UroNav predicate.

The NaviGo Workstation Version 2.0 is substantially similar to cleared Navigo in terms of technological characteristics and principles of operation. Both devices have the same following technological characteristics::

- To assist the physician by transfer and display of ultrasound images on the workstation screen
- To provide regional orientation information during prostate procedures
- To build, display and manipulate a 3D model of the prostate on screen
- To define the physician's ROIs (Regions Of Interest) and display them on the 3D model
- To archive procedure data and report generating
- To provide data management solutions
- To track, display and record trajectories
- To display the scanning history, including pathology analyses
- To retrieve and display DICOM compliant information
- To fuse DICOM compliant originated regions of interest with the ultrasound 2D and 3D information

Several modifications have been made from the primary predicate device, including the following:

The physician can now upload MR and CT DICOM studies from PACS and also from the hospital intranet file server to the Navigo workstation. . No modification of the original source documents on the intranet server is possible. Also, with this change it is possible to backup data from the Navigo workstation to the hospital intranet file server.

Addition of optional automatic segmentation and as a result the removal of the illustration model option.

Real-time prostate model overlay on the live US image with the ability to perform manual adjustments.

Addition of a Fusion review option which allows the physician to inspect the fusion result and make manual adjustments if needed.

Display of the US image parameters with manual setting capability.

The Navigo Workstation Version 2.0 includes a support to trans-perineal biopsy and an option for manual compensation procedure when it is not possible to use the reference sensor (e.g. Lithotomic position).

A table comparing the key features of the subject and predicate devices is provided below.

	Navigo Workstation Version 2.0	**Navigo Workstation (K160934)**	**Uronav (Version 2.0) (K153073)**
Indications for Use	The UC-Care Navigo Workstation is an adjunctive tool for ultrasound guided procedures and 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. The Navigo Workstation offers the ability to fuse DICOM originated information (e.g. MRI, CT) with the ultrasound images and thus superimposes information from one modality onto the other. It also provides the ability to display a simulated image of a tracked insertion tool such as a needle, guide wire, catheter, 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. Additional software features include patient data	The UC-Care Navigo Workstation is an adjunctive tool for ultrasound guided procedures and 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. The Navigo Workstation offers the ability to fuse DICOM originated information (e.g. MRI) with the ultrasound images and thus superimpose information from one modality onto the other. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3-D image registration. The device is specifically indicated to provide information on regional orientation within the prostate to assist needle targeted procedures (e.g.	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, multiplanar reconstruction, segmentation, image measurement and 3-D image registration, as well as storage and future retrieval of this information Navigo 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.	biopsy) regions of interest display, procedures planning and, reconstruction of a 3D rendered surface model of the prostate display needle locations that have been selected by the physician, as well as storage and future retrieval of this information.	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.
Product Code	LLZ	LLZ	LLZ
Device Classification	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
Target Anatomy	prostate	prostate	prostate
Anatomical Access	Transrectal & Trans-perineal	Transrectal	Transrectal & Trans-perineal
Software			
Windows O.S.	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	No	No	Yes
Multi-Planar Reformatting (MPR)	Yes	Yes	Yes
Motion Compensation			
Reference sensor	Yes	Yes	No
Connectivity			
DICOM	Yes	Yes	Yes
Ultrasound video	Yes	Yes	Yes
Review tools			
Standard 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
Plan / Mark Locations	Yes	Yes	Yes
Navigation Type	Electromagnetic	Electromagnetic	Electromagnetic

Performance Data

The performance characteristics of the Navigo Workstation Version 2.0 and its compliance with the applicable recognized standards were evaluated through the following testing:

- Software verification and validation testing
- Electrical safety testing
- EMC testing

Bench Testing

The following bench studies were performed in order to demonstrate that the Navigo Workstation Version 2.0 meets its specifications and its updated indications for use:

- 2D to 3D Correction (Manual adjustment): In order to validate that the correction defined by moving the model contour on the 2D image enables the user to correct the 3D model location in respect to the real time US image, the following testing was performed using a prostate phantom. A simulated shift was performed with the phantom, and the Navigo software was used to correct the shift. The location error of fusion ROIs in the model relative to their location in the US image were evaluated by measuring the distance between the US lesion center and ROI overlay center (i.e. location error). For all working scenarios (simple procedure, fusion and alignment with historic procedures), the manual adjustment enabled to overcome deviations in model location during procedure and return the model to the correct location within the required 3mm accuracy level.

- CT Compatibility: In order to validate that the Navigo Workstation Version 2.0 can read correctly the CT data to create a CT 3D model, testing was performed using prostate phantom. Phantoms were scanned both on MRI and on CT. For each phantom the DICOM CT series and MRI (T2) series were loaded in Navigo Fusion studio. Images from apex to base were selected and segmented. The 3D models generated by Navigo based on MRI and CT images were compared to evaluate volumes of the two models, the average gap between the surfaces (RMSE) and the maximum distance (local maximum). The results establish that the 3D models created from MRI data are equal to the equivalent 3D models created from the CT data within the acceptance criteria. Therefore, it can be concluded that the Navigo Workstation Version 2.0 is compatible with CT DICOM data.

- Navigo Fusion Accuracy testing – Trans-perineal Approach: To validate the Navigo Workstation Version 2.0 MRI fusion accuracy when used with the trans-perineal approach, testing was performed using two phantoms each containing randomly located isoechoic lesions. MRI scanning of the phantom was performed and loaded into the Navigo fusion studio, contours of the prostate and the lesions were marked. Trans-perineal Ultrasound (BK Flex focus, 8848) scan was then performed using the Navigo Workstation Version 2.0. 3 biopsy needles were then targeted into each

lesion by inserting the needle to the suggested trajectories. A 1 mm CT scan was performed post procedure to visualize the inserted needles within the isoechoic lesions. Accuracy was defined as the difference between the actual needle location as measured on CT and the targeted location as measured on the real time US images. All obtained results demonstrate that that the accuracy of the MRI fusion performed by the Navigo Workstation Version 2.0 when used with the trans-perineal approach meets the requirements of a location error < 3mm.

Conclusions

The Navigo Workstation Version 2.0 is substantially equivalence to the Navigo Workstation (K160934) and the Uronav Version 2.0 (K153073). The Navigo Workstation Version 2.0 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. The use of CT as a source for DICOM information is covered by the indications for use of the Uronav Version 2.0, and does not affect the device's diagnostic effect. In addition, the minor technological differences between the Navigo Workstation Version 2.0 and its predicate devices raise no new or different questions of safety or effectiveness. Performance data demonstrate that the Navigo Workstation Version 2.0 is as safe and effective as the cleared Navigo Workstation and provides the same level of accuracy. Thus, the Navigo Workstation Version 2.0 is substantially equivalent.