DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 6, 2017

UC-CARE Ltd.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K160934
Trade/Device Name: NaviGo™ Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 10, 2017
Received: January 10, 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.

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)*
K160934

Device Name
NaviGo™ Workstation

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) 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. 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.

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

NaviGo™ Workstation

510(k) Number K160934

Applicant's Name:

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Date Prepared:

January 10, 2017

Trade Name:

NaviGo™ Workstation

Classification Name:

Picture archiving and communications system.

Classification:

Picture archiving and communications systems have been classified as Class II devices, product code: LLZ, Regulation Number: 892.2050, reviewed by the Division of Radiology.

Predicate Devices:

Primary: NaviGo™ Workstation (UC-CARE Ltd.), cleared under K100784, concurrence date November 1, 2011.

Secondary: Urostation – 3D Prostate Suite (Koelis), cleared under K131448, concurrence date July 26, 2013.

Performance Standards:

No performance standards have been established for such a device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Device Description:

The NaviGo™ Workstation is an adjunctive tool in the management of prostate diagnostic and interventional procedures. The NaviGo™ Workstation allows prostate needle tracking, recording, and management solution. The NaviGo™ Workstation 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 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. The device includes means to compensate for patient body and prostate motion at any time during the procedure.

The NaviGo™ Workstation is designed to work with standard trans-rectal ultrasound systems and biopsy setup without changing or interfering with the physician's existing workflow. The NaviGo™ Workstation 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 for viewing and creation of a 3D model. As with any other procedure, the TRUS probe is used together with 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's screen. The NaviGo™ Workstation 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 biopsy results.

The NaviGo™ Workstation 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 model for segmentation of the ROI can be either an Ultrasound image frozen during the procedure or a DICOM complaint image from another imaging study completed prior to the Ultrasound procedure (e.g. MR) when selecting the fusion procedure to display the planned targets. The ROIs are clearly numbered and labeled by a letter symbolizing it 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.

During the procedure, the physician may change some of the parameters on the US system or perform different actions that require the NaviGo™ Workstation 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 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 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 the NaviGo™ is required to support.

In off-line mode, the NaviGo™ 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 report, and provides a DICOM (e.g. MRI) interface for ROI definition, 3D model display, and data communication.

Intended 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) 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. 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.

Comparison of Technological Characteristics:

The subject NaviGo Workstation device and the primary predicate NaviGo Workstation device have the same principles of operation and basic design. Both devices have the same following technological characteristics:

- assist the physician by transfer and display of ultrasound images on the workstation screen
- provide regional orientation information during prostate biopsy procedures
- build display and manipulate a 3D model of the prostate on screen
- archive procedure data and report generating
- provide data management solutions
- track, display and record the biopsy needle trajectory location retrieved from the ultrasound probe
- display the scanning history, including pathology analyses

Several modifications have been made from this predicate device, including the following: addition of illustration model (side-fire first procedure only), needle-fire recognition, image-state correction offline configuration, and end-fire ultrasound probe support. These modifications are considered minor and do not raise new issues of safety and efficacy.

Fusion functionality has been added to the subject NaviGo device, including fusion of DICOM originated information, ROI display, and procedure planning. The indications for use statement of the subject device has been modified from the predicate device to include the addition of fusion functionality. The fusion functionality of the subject NaviGo device is substantially equivalent to the fusion functionality of the secondary predicate Urostation device, including the stated accuracy of the system. Therefore, the addition of fusion functionality does not raise any safety or effectiveness concern in comparison with the cleared device.

Substantial Equivalence Comparison Table:

Product	**NaviGo (K100784) [Primary Predicate Device]**	**Urostation (K131448) [Secondary Predicate Device]**	**Subject NaviGo Device (K160934)**
Product code	LLZ	LLZ	LLZ
Class	II	II	II
Device Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
Visualization Means	Side-fire Ultrasound	End-fire Ultrasound	Side -fire & End-fire Ultrasound
Supported Modalities	Ultrasound	Ultrasound, DICOM images (e.g. MRI)	Ultrasound, DICOM images (e.g. MRI)
Accuracy	+/-5mm	+/-3mm	+/-3mm
Segmentation (Contouring)	Yes	Yes, only for fusion	Yes
3D model reconstruction	Yes, contouring only	Yes, only for fusion	Yes, illustration & contouring
Needle trajectory display	Real-time	Upon request	Real-time
Tracking technology	Electro-magnetic (mattress and cube)	Image processing	Electro-magnetic (cube only)
Offline	Post procedure data analysis, pathology results	Post procedure data analysis, pathology results, planning (on DICOM images)	Post procedure data analysis, pathology results, planning (on DICOM images)
Regions of interest	No	Originated from DICOM images (e.g. MRI)	Originated from US images + DICOM images (e.g. MRI)
Registration	US - US	US - US, and MR - US (fusion)	US - US, and MR - US (fusion)
DICOM connectivity	No	Yes	Yes

Non-clinical Performance Data:

The performance characteristics and operation/usability of the modified NaviGo™ Workstation were evaluated in the following non-clinical (bench) testing.

Fusion accuracy performance test:

The accuracy of targeting DICOM (MRI) derived regions of interest (ROI) by using the NaviGo Workstation was evaluated. . Four phantoms each with 3 isoechoic lesions (CIRS Model 778-05, containing 3 randomly located isoechoic lesions of 0.5 cc) were targeted 2-3 times each using the NaviGo MRI fusion algorithm. Two phantoms were targeted using side fire ultrasound probes and two phantoms were targeted using end fire ultrasound probes. Needle location were defined relative to the ROI center line and accuracy is defined as the difference in needle location between the needle trajectory (targeted location in lesion) as marked on the real time US image, to the actual result as seen in post procedure CT scan. A total of 34 ultrasound guided biopsies were targeted into 12 isoechoic lesions. All 34 biopsies (100%) successfully hit the target lesion with an average error of 1.32±0.84mm. 32.3% of the biopsies had accuracy of <1mm, 47% of the biopsies had an accuracy of 1 to 2mm, 20.6% of the biopsies had an accuracy of 2 to 3mm, and no biopsies had an error larger than 3mm. .

Illustration model performance test:

The accuracy of the illustrated (Fast) 3D prostate model in comparison to the full contours 3D prostate model was evaluated. 10 prostates were scanned using the NaviGo Workstation, and for each prostate a Fast 3D model and a full contours 3D model was created. Each pair of 3D models was compared for volume difference and root mean square error (representing the average distance between the surfaces). The prostate shape of the Fast model was found to be very similar to the prostate shape of the full contour model, with an average RMS error of 3.7±0.66mm between the surfaces. Volume calculations were also similar, with an average difference of 10.4%±5.15%. These results demonstrate the ability of the Fast model to provide the physician with a tool which requires minimum effort but still maintains good similarity to the full contour model.

Substantial Equivalence Conclusion:

In summary, the NaviGo™ Workstation is substantially equivalent to the previously cleared NaviGo™ Workstation (K100784) primary predicate device in all functionality except for fusion functionality. Modifications from the primary predicate device are minor and do not raise new issues of safety and efficacy. The fusion functionality of the subject NaviGo device is substantially equivalent to the fusion functionality of the secondary predicate Urostation device, including the stated accuracy of the system. Therefore, the addition of fusion functionality does not raise any safety or effectiveness concern in comparison with the cleared device. In summary, the subject NaviGo™ Workstation described in this submission is substantially equivalent to the NaviGo™ Workstation (K100784) predicate device and Urostation (K131448) predicate device.