August 7, 2025

UC-CARE Ltd.
℅ Avital Levertov
Consultant, RA Specialist
Gsap
POB 15038, Matam
Haifa, 3190500
Israel

Re: K250664
Trade/Device Name: Navigo Workstation 2.3 (FPRMC00039)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QTZ, LLZ
Dated: March 5, 2025
Received: March 5, 2025

Dear Avital Levertov:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250664

Device Name

Navigo Workstation 2.3 (FPRMC00039)

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. The software is not intended to predict ablation volumes or predict ablation success.

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.

July 20, 2025

510(k) Summary

UC-Care Ltd.'s Navigo Workstation Version 2.3 (FPRMC00039)

1. **Submitter Information**

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Date of Preparation: May 11, 2025

2. **Identification of Subject Device**

Name of Device: Navigo Workstation Version 2.3 (FPRMC00039)
Common or Usual Name: Navigo Workstation Version 2.3 (FPRMC00039)
Proprietary/Trade name: Navigo Workstation Version 2.3 (FPRMC00039)
Classification Name: Medical image management and processing system
Regulation Number: 21 CFR 892.2050
Product Code: QTZ, LLZ
Regulatory Class: II
510(k) Number: K250664

3. **Identification of Predicate**

Device Name	510(k) Number	Type
Navigo Workstation Version 2.0	K173054	Primary
Artemis	K222222	Reference

4. **Device Description**

The Navigo Workstation version 2.3, model: FPRMC00039 (hereinafter referred to as "Navigo Workstation Version 2.3") is an adjunctive tool in the management of prostate diagnostic and interventional procedures. The Navigo Workstation provides tracking, recording, and management solutions for prostate insertion tools (such as a needle[1], guide wire, or catheter).

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, CT) with the ultrasound images and thus superimposes information from one modality onto the other. The device includes means to compensate for the patient's body and prostate motion at any time during the procedure. In addition, the Navigo Workstation Version 2.3 supports treatment procedure by allowing the physician to plan the treatment by selecting a treatment needle with its defined properties (as declared by the manufacturer) and displaying the virtual ablation zone. The system enables the physician to segment anatomic ROIs (anatomic Regions Of Interest, e.g. surrounding organs) and present the distance measurements of the virtual treatment zone from it. The ROIs used for treatment planning can be either ROI segmented on MRI/CT images or positive pathology results updated on historic biopsy procedures performed on the Navigo.

The Navigo Workstation is used as an add-on to the ultrasound diagnostic and interventional procedures of the prostate gland. When operated in conjunction with the standard equipment in trans-rectal/trans-perineal ultrasound prostate procedure, the Navigo software may be used for the following:

- To assist the physician by transferring and displaying ultrasound images on the workstation screen
- To provide regional orientation information during prostate procedures
- To build a display and manipulate a 3D model of the prostate on a 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 the needle trajectory location retrieved from the ultrasound
- 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

[1] In this document, the needle is described as the insertion tool guided by Navigo; however, the information applies to any insertion tool, such as a guide wire or catheter, inserted through the same transducer needle guide.

- To support the grid trajectory in Grid guided procedures
- To perform automatic or manual compensation for patient movement.
- To support treatment procedure: The module allows pre-procedure planning, real-time display of the treatment needle virtual ablation zone, accurate placement of the needle or insertion tools (such as cryoprobes) on targets, 3D tracking, and distance measurements (proximity) to anatomic ROIs.

The Navigo Workstation Version 2.3 is designed to work with standard trans-rectal/ transperineal ultrasound systems and biopsy setup without changing or interfering with the physician's existing workflow. The Navigo Workstation Version 2.3 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 2.3 for viewing and creation of a 3D model. As with any other procedure, the Ultrasound 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 2.3 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 enable the 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.
In offline mode, the workstation allows analysis of previous procedures, updates to biopsy locations, report generation, and DICOM-based ROI definition. Offline tools support treatment planning by segmenting anatomical ROIs, displaying virtual treatment regions, and measuring distances from these regions to surrounding structures. Data from prior imaging or biopsy procedures can be utilized for planning.
The device consists of the following components and accessories: The Navigo Workstation cart, electromagnetic transmitter, probe sensor, reference sensor, grid-plate sensor, sensor fixators, reference sensor tape, and cables.

5. **Indications for Use Statement**

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**.**
The software is not intended to predict ablation volumes or predict ablation success.

6. **Summary of Technological Characteristics**

The subject device Navigo Workstation Version 2.3 has the same intended use and indications for use as its primary predicate device (Navigo Workstation Version 2.0, K173054).
Since the intended use and Indications for Use of the Navigo Workstation 2.3 remain the same as the primary predicate device (Navigo Workstation 2.0, K173054), the reference device (Artemis, K222222) was added to support the software aspects (technological characteristics) rather than the subject device's Indications for Use.

The Navigo Workstation Version 2.3 is substantially similar to primary predicate device Navigo Workstation (Version 2.0, K173054) in terms of technological characteristics and principles of operation.
Both devices share the following technological features:
Imaging Interface:
Both the subject and cleared devices interface with separate, cleared ultrasound systems that utilize ultrasound probes for imaging the prostate.
Electromagnetic Tracking System:
Both devices employ the same electromagnetic tracking system, incorporating identical sensors to integrate spatial position information onto ultrasound images based on the positioning of the ultrasound probe.
3D Prostate Model Capabilities:
Both devices allow the physician to:
Build, display, manipulate, archive, and retrieve a 3D model of the prostate.
Present the 3D model over the 2D ultrasound image on the workstation screen.
Biopsy Location Management:
Both the subject and cleared devices enable the physician to:
Select and mark suggested biopsy locations.
Display these suggested locations on the 3D prostate model.
DICOM Data Integration:
Both devices retrieve and display DICOM-compliant data (MRI/CT) and enable fusion of this data with 2D and 3D ultrasound images.

Needle/Insertion Tool Tracking:
Both devices support the tracking, display, and recording of needle/insertion tool trajectory locations.
Procedure Data Management:
Both devices provide functionality to:
Archive and retrieve procedure data.
Mark retrieved biopsy locations with updated pathology results.
Generate comprehensive reports.
This demonstrates that the Navigo Workstation Version 2.3 retains the same core technological characteristics and operational principles as the cleared predicate device

Several modifications have been made to the primary predicate device, including the following:
Software modifications and Feature Expansions
The company has added software features that expand upon existing functionalities in the Navigo Workstation version 2.0 (K173054, predicate device):

- Software expansion to allow labeling of anatomic Regions of Interest (ROIs)
- Software expansion to load previous biopsies with positive pathology results as ROIs
- Software expansion to enable the option to skip manual measurement and use system measurement instead

Additional key software modifications include:

- Software modification to add margin to ROIs and positive biopsies
- Display of the treatment needle virtual ablation zone
- Enabling distance measurements (proximity) to anatomical ROIs

Differences between the systems to address software changes to the viewing and display options were evaluated in the same manner as the testing performed to evaluate the cleared Navigo and do not affect the device safety and effectiveness.

Hardware modifications
The subject device, Navigo Workstation 2.3 (model FPRMC00039), includes several hardware modifications due to the end-of-life (EOL) status of certain components. While the isolation transformer remains unchanged, the cart has been replaced with an equivalent off-the-shelf model. Additionally, the computer, frame grabber, and touchscreen have been updated with current components that provide the same functionality as the original ones.

The differences between the Navigo Workstation 2.3 cart (model FPRMC00039), and the cart of the cleared Navigo Workstation 2.0 (model FPRMC0016A), are mainly related to changes in the physical form factor of the subject device. The subject device now utilizes a smaller mechanical enclosure, which enhances portability.

These differences between the Navigo Workstation 2.3 and Navigo Workstation 2.0 do not impact the device's safety or effectiveness.

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

Substantial Equivalence (Comparison Table)

	Subject Device: Navigo Workstation Version 2.3	**Primary Predicate** Device: Navigo Workstation Version 2.0 (K173054)	**Reference Device:** Artemis (K222222)
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	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	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

	Subject Device: Navigo Workstation Version 2.3	**Primary Predicate Device:** Navigo Workstation Version 2.0 (K173054)	**Reference Device:** Artemis (K222222)
	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. The software is not intended to predict ablation volumes or predict ablation success.	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.	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

	Subject Device: Navigo Workstation Version 2.3	**Primary Predicate** Device: Navigo Workstation Version 2.0 (K173054)	**Reference Device:** Artemis (K222222)
			procedures information and outcomes. Artemis Cryo Treatment Planning module is an add on to the existing Artemis software that allows physicians to prepare for cryo treatment planning based on positive pathology cores obtained during Artemis guided biopsies and registration results with other imaging modalities such as MRI, CT. The module allows accurate placement of cryo probes on targets, 3D tracking, real-time feedback on extend of cryo ice formation. The technology provided by Artemis generates ice models based on the specifications provided by the cryo device manufacturers and displays the models on the live ultrasound to provide guidance to the users during the procedure. The module also allows outlining or segmenting other organs that surround the prostate. Organs include bladder and urethra.

	Subject Device: Navigo Workstation Version 2.3	**Primary Predicate** Device: Navigo Workstation Version 2.0 (K173054)	**Reference Device:** Artemis (K222222)
Primary Product Code	QTZ[2]	LLZ	QTZ
Primary Regulation Number	21 CFR § 892.2050	21 CFR § 892.2050	21 CFR § 892.2050
Class	II	II	II
Target Anatomy	prostate	prostate	Prostate
Anatomical Access	Transrectal & Transperineal	Transrectal & Transperineal	Transrectal & Transperinea
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

[2] The primary product code for the subject device (Navigo Workstation 2.3) is **QTZ**. This code was not available at the time of the original submission for the primary predicate device (Navigo Workstation 2.0). The difference in product code assignment between the subject device and the primary predicate device reflects updates to FDA's product classification system and does not indicate a change in intended use or technological characteristics. The product code **LLZ**, which was previously assigned to the primary predicate device, has been designated as the secondary product code for the subject device.

	Subject Device: Navigo Workstation Version 2.3	**Primary Predicate** Device: Navigo Workstation Version 2.0 (K173054)	**Reference Device:** Artemis (K222222)
Multi-Planar Reformatting (MPR)	Yes	Yes	Yes
Motion Compensation			
Reference sensor	Yes	Yes	No
Connectivity			
DICOM (Retrieve/Store)	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	Mechanical

Non-Clinical Performance Testing

The performance characteristics of the Navigo Workstation Version 2.3 and its compliance with the applicable recognized standards were evaluated through the following testing:

- Software verification and validation testing
  IEC 62304 Edition 1.1 2015-06, `Medical device software - Software life cycle processes'
- Electrical safety testing
  IEC 60601-1 Edition 3.2 2020-08, `Medical electrical equipment - Part 1: General requirements for basic safety and essential performance'
- EMC testing
  IEC 60601-1-2 Edition 4.1 2020-09, `Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests'
  IEC TR 60601-4-2 Edition 1.0 2016-05, `Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems'
- Risk and Usability
  ISO 14971 Third Edition 2019-12, `Medical devices - Applications of risk management to medical devices'
  IEC 60601-1-6 Edition 3.2 2020-07, `Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability'

Bench Testing:

Performance tests were conducted by UC Care in order to validate the changes presented in this 510(k) Submission using well established methods based either on recognized consensus standards or UC Care's internal existing test methods previously utilized for legally marketed devices. No deviations took place during the tests.

The tests were as follows:

- Mesh Proximity Test
  A bench test was conducted to validate the accuracy of the proximity measurements between the treatment zones created by applicators (referred to as the "ice-ball") and anatomical regions of interest (ROIs), such as the bladder or urethra. This assessment is integral to the Pre-Procedure Treatment Planning feature, which calculates the shortest distance between two 3D shapes: the treatment zone and the labeled ROIs.
  UC-Care developed an algorithm for this purpose, which computes the proximity between two 3D models represented as sets of triangular elements.
- Tests for Margin of ROIs and Positive Biopsies
  A bench test was performed to validate the software's capability to accurately add margins to regions of interest (ROIs) and positive biopsies, ensuring consistency across various clinical scenarios. The process utilizes a specialized algorithm designed to generate a margin around an ROI mesh.

- Tests for Virtual Ablation Zone Display of the Treatment Needle
  A bench test was conducted to validate the accuracy of the virtual ablation zone display and its alignment with the specifications provided by needle manufacturers. The feature includes a visual virtual display of the Cryo treatment zone (commonly referred to as the "ice ball"). Needle manufacturers provide specifications for the expected treatment zones and isotherms for each needle. Navigo Workstation 2.3 displays the virtual ablation zone in both 3D (within the prostate model) and as a projection on the 2D ultrasound image.
- Mechanical Testing for Navigo Workstation model FPRMC00039
  A bench test was conducted to validate the performance and functionality of updated components in the Navigo system (model FPRMC00039), ensuring compliance with defined requirements. The study included tests such as component stability, system functionality, vibration testing, temperature testing, and load testing.

Clinical Test

No clinical Study was performed for the purpose of this submission.
Clinical performance data was not required to demonstrate safe and effective use of Navigo workstation 2.3.

Conclusions

The Navigo Workstation Version 2.3 is substantially equivalent to its predicate device (the cleared Navigo Workstation Version 2.0, K173054). The Navigo Workstation Version 2.3 has the same intended uses and indications for use as its predicate device, as well as similar technological characteristics and principles of operation. The technological characteristics of Navigo Workstation Version 2.3 are similar to those of its predicate device and are also supported by the reference device (Artemis, K222222).
The technological differences between the Navigo Workstation Version 2.3 and its predicate device do not raise new or different questions of safety or effectiveness.
Performance data demonstrate that the Navigo Workstation Version 2.3 is as safe and effective as the cleared Navigo Workstation 2.0 when used as labelled, and provides the same level of accuracy. Thus, the Navigo Workstation Version 2.3 is substantially equivalent to its predicate (Navigo Workstation Version 2.0).