Philips DS North America LLC
Sagar Pimpalwar
Sr.Manager, Regulaory Affairs
3630 SW 47th Avenue
Gainesville, Florida 32608

June 5, 2025

Re: K250800
Trade/Device Name: UroNav 4
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, QTZ
Dated: March 13, 2025
Received: March 14, 2025

Dear Sagar Pimpalwar:

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)*

K250800

Device Name

UroNav 4

Indications for Use *(Describe)*

UroNav is a stereotaxic medical device intended to assist the clinician with planning and guidance for clinical, interventional and/or diagnostic procedures for biopsy and/or soft tissue ablation.
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, multi-planar reconstruction, segmentation, image measurements and 2D/3D image registration. UroNav is indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland.
The software is not intended for diagnosis. 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.

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K250800

510(k) Summary

UroNav 4

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K250800
510(k) SUMMARY
UroNav 4

Date: 5/20/2025

Company's Name and Address
Philips DS North America LLC
3630 SW 47th Avenue
Gainesville FL 32608
United States

Contact Person
Sagar Pimpalwar
Sr. Manager, Regulatory Affairs
Philips - Clinical Informatics
Email: sagar.pimpalwar@philips.com
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Device Trade Name
UroNav 4

Classification
Classification Regulation: 21 CFR 892.2050
Classification Panel: Radiology
Device Class: Class II
Product code & Classification name

- **Primary:** LLZ - System, Image Processing, Radiological
- **Secondary:** QTZ - Radiological image processing software for ablation therapy planning and evaluation

Predicate Device:
Classification Name: System, Image Processing, Radiological
Classification Regulation: 21 CFR 892.2050
Classification Panel: Radiology
Device Class: Class II
Product code: LLZ
510(k) Clearance: K193403, December 27th, 2019.

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Device Description and Technological Characteristics

The system assists physicians in guiding interventional instruments to pre-defined targets, which may be identified pre-procedurally or intra-procedurally using imaging data or relative to a designated position on the patient.

As an image fusion system, UroNav combines pre-procedural imaging, such as Magnetic Resonance Imaging (MRI), with real-time intra-procedural imaging from ultrasound (US) systems. This fusion capability enables precise localization of areas of interest detected in one imaging modality and maps them onto another. The system also facilitates spatial registration between two-dimensional (2D) and three-dimensional (3D) imaging datasets and between imaging data and physical patient space.

The UroNav 4 System includes the following components:

- **Electromagnetic Measurement System (EMMS):** Comprising a Field Generator, System Control Unit, and System Interface Unit(s) for electromagnetic tracking.
- **System Unit:** Incorporating a central processing unit (CPU), monitor, medical-grade power supply, mobile cart, and UroNav software.
- **Field Generator Stand:** Ensuring stability for electromagnetic tracking during procedures.
- **Software Features:** Patient data management, multiplanar reconstruction, segmentation, image measurement tools, and 3D image registration capabilities.
- **Compatible Devices:** Compatible with commercially available ultrasound machines, probes, needle guides, biopsy devices, and applicators.

The system reconstructs 3D ultrasound images from live 2D video streams connected to ultrasound systems. Clinicians can select targets and navigate instruments with precision through its interactive interface, which features a keyboard, mouse, and visual display. The UroNav system supports diverse clinical environments, such as hospital operating rooms, outpatient surgery centers, ultrasound suites, and procedure rooms.

The UroNav 4 design ensures compatibility with existing clinical workflows by utilizing commercially available ultrasound machines and accessories.

Additional software functionalities include patient data management, multiplanar reconstruction of images, segmentation tools for enhanced visualization, image measurements, and 3D image registration.

The UroNav 4 System is intended to aid physicians in performing minimally invasive diagnostic and therapeutic procedures by providing real-time image-guided navigation. It is not intended to replace physician judgment.

Indication of Use

UroNav is a stereotaxic medical device intended to assist the clinician with planning and guidance for clinical, interventional, and/or diagnostic procedures for biopsy and/or soft tissue ablation. 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, multi-planar reconstruction, segmentation, image measurements, and 2D/3D image registration. UroNav is indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland.
The software is not intended for diagnosis.
The software is not intended to predict ablation volumes or predict ablation success.

Substantial Equivalence

UroNav 4 is as safe and effective as its predicate device. Both devices have similar indications for use, technological characteristics, and principles of operation. The minor technological differences between the UroNav and its predicate device raise no new safety or effectiveness issues.

The predicate UroNav System was initially marketed for the placement of fiducial markers. Subsequently, these indications were removed and will not be included in the indications for use of UroNav 4. All other indication for use remain unchanged

The UroNav 4 has the same fundamental technological characteristics as the predicate. A summary of features is as follows:

- **Multi-Modality Support**: Enables integration of different imaging modalities for comprehensive visualization
- **Image 2D/3D Review**: Provides capability to review both 2D and 3D images
- **3D Rendering View**: Offers three-dimensional visualization of anatomical structures

- **Live 2D Ultrasound**: Delivers real-time ultrasound imaging capabilities
- **Gland Segmentation**: Allows for isolation and visualization of specific glandular structures
- **Image Registration**: Enables alignment of images from different modalities or time points
- **Rigid Registration**: Provides capability for non-deformable image alignment
- **Elastic Registration**: Allows for deformable image alignment to account for tissue movement
- **Multi-Planar Reformatting**: Enables viewing of 3D data in different planes
- **Mains Powered**: Operates using standard electrical power supply

The table below summarizes the substantive feature/technological similarities and differences between the subject and predicate device.

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Attribute	Primary Predicate Device UroNav System (K193403)	Subject Device UroNav 4
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Product Code	LLZ	Primary: LLZ Secondary: QTZ
Regulation Description	System, Image Processing, Radiological	LLZ: System, Image Processing, Radiological QTZ: Radiological image processing software for ablation therapy planning and evaluation
Regulation Number	892.2050	892.2050
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 (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	UroNav is a stereotaxic medical device intended to assist the clinician with planning and guidance for clinical, interventional and/or diagnostic procedures for biopsy and/or soft tissue ablation. 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

Attribute	Primary Predicate Device UroNav System (K193403)	Subject Device UroNav 4
	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.	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 indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland. The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.
Target Anatomy	Prostate	Prostate
Patient Population	Not explicitly defined	Adult males at risk for prostate disease who are deemed eligible for diagnostic MRI scan
Anatomy access	Transrectal & Transperineal	Transrectal & Transperineal
Software	• Microsoft Windows OS	Microsoft Windows OS
Key Technological Features	• Multi-Modality Support • General Image 2D/3D Review • 3D Rendering View • Live 2D Ultrasound • Gland Segmentation	• Multi-Modality Support • General Image 2D/3D Review • 3D Rendering View • Live 2D Ultrasound • Gland Segmentation

Attribute	Primary Predicate Device UroNav System (K193403)	Subject Device UroNav 4
	• Image Registration • Rigid Registration • Elastic Registration • Multi-Planar Reformatting • Mains Powered	• Image Registration • Rigid Registration • Elastic Registration • Multi-Planar Reformatting • Mains Powered
Review Tools	• Standard Image Viewing Tools • Measurement Tools • Segmentation Tools • Reporting Tools • Video Capture • Image Overlays • Annotation Tools	• Standard Image Viewing Tools • Measurement Tools • Segmentation Tools • Reporting Tools • Video Capture • Image Overlays • Annotation Tools • Advanced Annotation Tools - New

Non-Clinical Summary

UroNav 4 has undergone comprehensive non-clinical testing to ensure compliance with relevant FDA-recognized consensus standards and to demonstrate substantial equivalence to its predicate device. The following is a summary of the non-clinical tests performed:

- **Software Functionality**: Regression testing was conducted to verify existing features and validate new functionalities, including advanced annotation workflows and electromagnetic (EM) tracking accuracy. This test was performed per IEC 62304: Medical Device Software Lifecycle Processes.
- **Usability/Human Factors**: User interface updates were validated to ensure compliance with usability engineering standards (IEC 62366-1) and clinical workflow requirements. This included testing for biopsy workflow functionality, advanced annotation workflow, and kiosk mode validation.
- **Safety**: Testing activities focused on ensuring UroNav 4 does not pose risks to patients or users. This included validation of data encryption, access control mechanisms, and compliance with HIPAA standards.
- **System Compatibility**: Data migration testing ensured a seamless transition from UroNav 3.0 to 4.3, confirming no data loss or corruption during the upgrade process.
- **EM Tracking Accuracy**: To ensure the precision and reliability of the system during clinical procedures, the electromagnetic (EM) tracking accuracy was rigorously evaluated

- **Advanced Annotation Workflow Validation**: This test evaluated annotation dimensions, volumes, discretization errors, percent coverage estimation, and constraint-driven planning. Results confirmed that all advanced annotation functionalities meet predefined acceptance criteria.
- **Kiosk Mode Validation**: The kiosk mode was validated to ensure secure user authentication and access control mechanisms, enhancing system security.
- **Privacy and Security Compliance**: Testing verified that the system meets regulatory requirements for data protection (HIPAA) and cybersecurity.
- **Automated Testing**: Automated tests were conducted for both the advanced annotation workflow and biopsy workflow functionality to ensure all test cases pass without errors.

The non-clinical evidence shows that all critical functions, workflows, and safety measures work as intended. Validation activities confirmed that all entry and exit criteria defined in the Product Validation Plan were met without deviations or residual risks exceeding acceptable limits.

The non-clinical testing results support the conclusion that UroNav 4 is substantially equivalent to its predicate device, raising no new safety or efficacy concerns.

Conclusion:

Based on the technological characteristics of the devices, Philips DS North America LLC believes that UroNav 4 and the predicate device selected are substantially equivalent and do not raise new safety or effectiveness issues.