August 16, 2026

Lucida Medical, Ltd.
Toby Davis
VP of Engineering
Future Business Centre
King's Hedges Rd.
Cambridge, CB4 2HY
United Kingdom

Re: K253794
Trade/Device Name: Prostate Core™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 15, 2026
Received: June 15, 2026

Dear Toby Davis:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

NINGZHI LI -S Digitally signed by NINGZHI LI -S

for
Daniel M. Krainak, Ph.D
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253794

Please provide the device trade name(s).

Prostate Core™

Please provide your Indications for Use below.

Prostate Core™ is a software medical device intended for automatic segmentation and volumetric quantification of the prostate. Prostate Core™ is intended to be used by trained healthcare professionals as an aid to reading/assessing prostate MRI images of adult males aged 22 or over. Prostate Core™ is not intended as a replacement for clinical review or of the judgement of healthcare professionals. The software does not modify the original medical images and does not provide a direct diagnosis.

Prostate Core™ is not intended for patients:
- who received a prostate biopsy within 6 weeks before the MRI examination
- with prior prostate or urethral treatment or surgery that substantially affects the prostate gland
- whose MRI scan quality is severely impaired, for example by patient motion, breathing, peristaltic motion, rectal gas, or metallic implants such as hip prostheses
- where a radiologist considers that the MRI examination is not of diagnostic quality
- with MRI examinations that substantially deviate from PI-RADS®v2.1 scanning protocols
- whose MRI images have been captured using an endo-rectal coil.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

K253794

Date of summary:	5th August 2026
Submitter's name:	Lucida Medical Ltd
Submitter's address:	Lucida Medical Ltd, Future Business Centre, King's Hedges Road, Cambridge. CB4 2HY. United Kingdom
Submitter's contact:	Toby Davis
Telephone number:	+44-1223-921904

Device Proprietary Name:	Prostate Core™
Device Common Name(s):	Medical image management and processing system
Classification Name:	Class II
Product Code:	QIH
Regulation No:	21 C.F.R. §892.2050
Classification Panel:	Radiology Devices

Prostate Core is Substantially Equivalent to the following Legally Marketed device:

Legally Marketed Predicate Devices

510(k) Number	Trade Name	Manufacturer	Product Code
K203582	**qp-Prostate**	**Quibim S.L**	**LLZ**

Device Description

Prostate Core™ is a software-only medical device intended for the automated segmentation and volumetric measurement of the prostate gland from prostate magnetic resonance imaging (MRI) data.

Prostate Core™ uses a deep learning–based algorithm to automatically segment the entire prostate gland from DICOM-formatted MRI studies and to calculate the corresponding gland volume. The algorithm is based on a convolutional neural network architecture that operates on image data to generate segmentation outputs. The model is a locked algorithm that does not adapt or learn from new data during clinical use. Model development included training and validation on independent, multi-center datasets with expert radiologist annotations, and the final model is fixed at the time of release.

Prostate Core™ supports prostate MRI studies acquired on 1.5T and 3T scanners from major

manufacturers (e.g., Siemens, GE Healthcare, Philips) using acquisition protocols consistent with PI-RADS v2.1. Prostate Core™ is not patient-contacting and does not include any hardware components or accessories. The device operates as an image processing tool and does not perform computer-aided detection (CADe) or computer-aided diagnosis (CADx). It does not analyze, score, or characterize lesions, nor does it generate heatmaps or lesion-specific outputs.

Prostate Core™ is designed to be integrated into the clinical imaging workflow and does not include a graphical user interface. Outputs are viewed via the healthcare facility's Picture Archiving and Communication System (PACS) or other image management platforms. Following processing, the segmentation mask and volumetric data are exported in standardized DICOM formats (including DICOM-SEG and RTSTRUCT) to the PACS or other designated systems for storage, review, and subsequent clinical interpretation by appropriately trained healthcare professionals.

Prostate Core™ uses a modular, pipeline-based architecture developed in Python 3, employing industry-standard libraries for medical imaging and AI inference, including PyTorch.

Prostate Core™ is deployed on-premises, on a hospital server connected to the local imaging network.

Prostate Core™ includes the following key components:

1. Data Loading Module: Receives and validates DICOM-formatted MRI input data and allows specification of relevant MRI sequences (T2 axial, ADC axial, high B-value axial) as required by varying site protocols.
2. Segmentation Module: Applies a validated deep learning algorithm to generate a whole-gland prostate segmentation.
3. Volume Calculation Module: Computes the prostate gland volume (in milliliters) derived from the segmentation mask
4. Export Module: Converts the segmentation and volumetric data into standardized DICOM outputs for transfer to the PACS or compatible imaging systems.

Inputs: any DICOM-compliant prostate MRI data that meets PI-RADS v2.1 imaging standards.

Output: DICOM-SEG and RTSTRUCT files containing segmentation masks and volumetric measurements, fully compatible with common PACS and radiology workstations.

Technological Characteristics

Prostate Core™ is a software-only medical device that performs automated segmentation and volumetric quantification of the prostate from T2-weighted MRI images. Prostate Core™ utilizes a supervised deep learning algorithm based on a convolutional neural network architecture to generate voxel-level probability maps that are converted into a binary prostate segmentation. The processing pipeline includes image pre-processing and post-

processing steps to improve segmentation consistency and reduce false positives.

Prostate Core™ receives DICOM-format MRI data via standard DICOM networking interfaces and outputs DICOM-compliant segmentation objects (e.g., DICOM SEG, RTSTRUCT) and structured reports, including prostate volume measurements. The software is deployed within a healthcare provider network environment and interfaces with PACS or other designated DICOM systems for data input and output. The device does not modify original images and does not retain patient data after processing. The algorithm has been trained and validated using multi-center datasets with expert radiologist consensus annotations, and performance has been evaluated using established quantitative metrics for segmentation accuracy and volumetric agreement, consistent with similar automated image analysis devices.

Indications for Use

Prostate Core™ is a software medical device intended for automatic segmentation and volumetric quantification of the prostate. Prostate Core™ is intended to be used by trained healthcare professionals as an aid to reading/assessing prostate MRI images of adult males aged 22 or over. Prostate Core™ is not intended as a replacement for clinical review or of the judgement of healthcare professionals. The software does not modify the original medical images and does not provide a direct diagnosis.

Prostate Core™ is not intended for patients:

- who received a prostate biopsy within 6 weeks before the MRI examination
- with prior prostate or urethral treatment or surgery that substantially affects the prostate gland
- whose MRI scan quality is severely impaired, for example by patient motion, breathing, peristaltic motion, rectal gas, or metallic implants such as hip prostheses
- where a radiologist considers that the MRI examination is not of diagnostic quality
- with MRI examinations that substantially deviate from PI-RADS®v2.1 scanning protocols
- whose MRI images have been captured using an endo-rectal coil.

Substantial Equivalence Discussion

The subject device and the predicate device, qp-Prostate (K203582), are both Class II, software-only PACS tools intended for the processing of prostate MR images and adjunctive information for review by trained healthcare professionals. Neither device is intended for diagnostic use or as a stand-alone clinical decision support system. Both use DICOM MRI inputs, integrate with PACS, and output quantitative data for radiologist interpretation.

There are important differences between the subject device and the predicate device.

The subject device is limited to automated prostate segmentation and volumetric measurement, whereas the predicate also provides perfusion/diffusion analysis and structured reporting. This difference does not introduce any new or different type of risk as the subject device offers a subset of the predicate functionality, limiting the complexity and the risks associated with the additional functionality.

The predicate device (qp-Prostate (K203582)) includes a user interface and features to enable visualization, editing and review of segmentation results, while the subject device exports segmentation outputs directly to PACS or or other designated DICOM system, without a dedicated GUI. The absence of a GUI is a workflow choice that simplifies integration into existing PACS environments and is accompanied by suitable labeling to ensure that output segmentations are reviewed prior to onward use. This design reflects a workflow configuration difference rather than a difference in intended use or risk profile. Appropriate labeling ensures that segmentation outputs are reviewed by qualified healthcare professionals prior to clinical use.

Both subject and predicate devices are standalone software devices which process DICOM compliant MR images and output prostate segmentation and quantitative volumetric results.

A technical difference: The subject device uses a deep learning–based algorithm for automatic whole-gland segmentation while the predicate device uses automated prostate segmentation techniques. Despite this technological difference, both devices perform the same fundamental clinical task and produce equivalent types of outputs.

The performance of the subject device has been validated against expert reference standards using established quantitative metrics, demonstrating accuracy within clinically acceptable limits for adjunctive use. This technical difference does not raise new questions of safety or effectiveness. Automated segmentation of anatomical structures from MRI data is a well-established methodology, and the performance of the subject device has been validated against expert manual segmentation reference standards using accepted quantitative metrics, including Dice similarity coefficient and volumetric error analysis.

Validation studies demonstrate that the subject device achieves clinically acceptable accuracy for prostate segmentation and volumetric measurement. Performance testing was conducted using multi-vendor MRI datasets and compared against independently generated expert manual segmentations. Results demonstrate that the device performs reliably within clinically

acceptable limits for adjunctive use.

Therefore, although technological differences exist, these differences do not introduce new questions of safety or effectiveness. The subject device is as safe and effective as the predicate device qp-Prostate (K203582) and is substantially equivalent

Feature	**Subject Device (Prostate Core™)**	**Predicate Device (qp-Prostate, K203582, LLZ)**
Regulation / Product Code	21 CFR 892.2050, PACS, Class II, QIH	21 CFR 892.2050, PACS, Class II, LLZ
Intended Use / Indications	Automated segmentation and volumetric measurement of the prostate gland from MRI; adjunctive, not diagnostic; reviewed by qualified professionals.	Image viewing, processing, and analysis of prostate MRI; includes ADC and perfusion maps, segmentation, structured reporting; adjunctive, not diagnostic.
Inputs	DICOM-formatted prostate MRI (1.5T/3T, PI-RADS v2.1 compliant).	DICOM prostate MRI (T2 + DWI and/or DCE).
Outputs	DICOM-SEG and RTSTRUCT prostate masks and gland volume (ml), DICOM reports including Structured Reports	ADC and perfusion maps, segmentation masks, structured reports.
Segmentation Method	Deep learning AI for whole-gland segmentation.	Automated prostate segmentation algorithm.
Automation	Fully automatic; no manual interaction.	Automated but allows user verification/editing.
User Interface	None; outputs only to PACS or other designated DICOM systems.	Web-based viewer, structured reporting GUI.
Workflow Integration	On-premises server encrypted DICOM transfer; outputs routed to PACS or other designated DICOM systems.	On-premises client-server model; PACS query/retrieve; browser access

Performance Data	Validated on multi-vendor MRI datasets; metrics include Dice coefficient and volumetric error.	Validated on prostate MR datasets; compared against Olea Sphere.

Performance Data

The following performance data were provided in support of this submission.

Software Verification and Validation Testing

Non-clinical software verification and validation testing was conducted in accordance with a defined software development lifecycle consistent with IEC 62304 and ISO 14971. Testing demonstrated that the device meets its software system requirements, product requirements, and user needs.

Verification activities included unit, integration, and system-level testing. System-level testing was performed in a representative healthcare IT environment and included end-to-end validation of device operation from data input through to output generation.

Testing included:

- DICOM data handling and interoperability testing, including receipt of input MRI studies from PACS systems and transmission of output segmentation results (e.g., DICOM-SEG, RTSTRUCT) to external systems.
- Data validation and error handling, including rejection of incomplete, invalid, or non-DICOM inputs and verification of safe system behavior in these scenarios.
- Configuration and workflow testing, including verification of correct routing of outputs to configured destinations.
- Algorithm integration testing, confirming correct execution of the processing pipeline and generation of segmentation and volumetric outputs.

Cybersecurity and Network Communication Testing

Cybersecurity-related verification activities were conducted to ensure secure handling of patient data and protection of device functionality within a networked environment. Testing included:

- Verification of secure data transmission, including Transport Layer Security (TLS) implementation for DICOM communication
- Validation of system behaviour under secure and non-secure configurations, including appropriate handling of configuration settings
- Assessment of data integrity protections, ensuring that input data is validated prior to processing and that outputs are not generated from invalid or incomplete data
- Verification of system behaviour under fault conditions, including network interruption and communication failure scenarios

Bench (non-Clinical) and System Testing

For this software-only device, bench testing consists of non-clinical system and interoperability testing performed using representative datasets and simulated clinical workflows.

Testing includes end-to-end processing of prostate MRI studies from input through segmentation and output generation, verification of compatibility with multi-vendor MRI data (e.g., Siemens, GE Healthcare, Philips), validation of output formats (DICOM-SEG, RTSTRUCT, structured reports) for compatibility with standard PACS systems and verification of system performance across a range of imaging conditions and acquisition parameters

These testing activities demonstrate that the device performs as intended within its operating environment and that risks associated with interoperability, data handling, and network communication are appropriately controlled.

Stand-alone Performance Testing

No prospective clinical study was conducted to support this submission. Clinical performance was established through non-clinical evaluation using retrospectively collected clinical imaging data. The level of evidence is consistent with an observational study using retrospectively collected clinical imaging data and a reference standard derived from expert radiologist consensus.

The device was evaluated using independent, multi-center datasets of T2-weighted prostate MRI studies representative of the intended use population, including variation in scanner types, imaging protocols, and patient characteristics. Ground truth segmentations were established using consensus annotations from multiple expert radiologists with relevant subspecialty expertise.

Performance was assessed using established quantitative metrics for medical image segmentation, including Dice similarity coefficient (DSC), mean surface distance (MSD), and relative absolute volume error (RAVE). Results from both internal testing and independent external validation datasets demonstrated that predefined acceptance criteria were met for segmentation accuracy and volumetric agreement, supporting the device's performance as an aid to the assessment of prostate MRI.

AI/ML Algorithm Validation and Performance

The device incorporates a locked, supervised deep learning algorithm for automated prostate segmentation and volumetric quantification. The algorithm was developed using annotated prostate MRI datasets. The final model is fixed at release and does not perform continuous or adaptive learning in the field.

Training Data:

The algorithm was trained using a multi-source dataset comprising public and proprietary data, including PROSTATEx, PAIR-1, PRIME, and U.S. clinical datasets. Training included 775 cases, all with expert-annotated prostate segmentations.

Validation Data and Study Design:

Performance validation was conducted using independent datasets not used in model development, ensuring separation between training and test data. Evaluation included:

- Internal testing dataset: 70 patients
- External validation dataset: 100 patients
- Total validation population: 170 patients

The study design is consistent with a retrospective observational study using independently collected clinical imaging data.

Ground truth was established using consensus annotations from three expert radiologists, with voxel-wise agreement used to define the reference standard.

Dataset Characteristics:

The validation datasets were designed to be representative of the intended use population and clinical imaging conditions, including:

- **Age:** Mean ~66–67 years (range ≥42 years)
- **Sex:** Male patients (consistent with prostate imaging population)
- **Ethnicity/Race:** Includes White/Caucasian, Black/African American, Hispanic/Latino, and cases with unavailable ethnicity data
- **Geographic distribution:** Multi-site data from the United States and United Kingdom
- **Clinical subgroups:** PIRADS categories (1–5)
- **Scanner manufacturers:** Siemens, GE Healthcare, Philips
- **Magnetic field strength:** 1.5T and 3T
- **Other variables:** BMI, site type (academic and community), and imaging protocol variability

All validation datasets were independent of the development and training datasets and were not accessible to the algorithm development team during model development or training. External validation data were held out specifically for regulatory performance evaluation.

Imaging Protocols:

All cases consisted of **T2-weighted prostate MRI** acquired using standard clinical protocols consistent with PI-RADS v2.1 recommendations. Imaging parameters included:

- In-plane resolution ≤ 0.8 mm
- Slice thickness ≤ 4 mm
- Whole prostate coverage
- Multi-vendor and multi-site acquisition

Performance Metrics and Acceptance Criteria:

Algorithm performance was evaluated using established quantitative segmentation metrics:

- **Dice Similarity Coefficient (DSC)** – overlap accuracy
- **Mean Surface Distance (MSD)** – boundary accuracy
- **Relative Absolute Volume Error (RAVE)** – volumetric accuracy

Predefined acceptance criteria across the whole dataset were:

- **DSC ≥ 0.90**
- **MSD ≤ 0.7 mm**
- **RAVE ≤ 7.09%**

Performance Results

Performance on independent validation datasets demonstrates that all predefined acceptance criteria were met for the overall validation dataset. Subgroup analyses demonstrated generally consistent performance across clinically relevant demographic, imaging and clinical categories.

External Validation Dataset (n = 100):

- DSC: Median 0.93 (95% CI: 0.92–0.93)
- MSD: Median 0.27 mm (95% CI: 0.25–0.28)
- RAVE: Median 3.99% (95% CI: 3.17–4.80)

Internal Testing Dataset (n = 70):

- DSC: Median 0.92
- MSD: Median 0.28 mm
- RAVE: Median 4.60%

Subgroup Analysis

Performance was evaluated across clinically relevant subgroups, including PIRADS categories, scanner manufacturer and field strength, geographic region and patient demographics. Results demonstrated consistent performance across racial, ethnic and PI-RADS scoring subgroups, and across scanner types. One geographic subgroup (US Midwest, n = 4) had a median RAVE value exceeding the predefined whole-dataset acceptance threshold. Given the very small subgroup size, this isolated finding was not considered indicative of a systematic reduction in device performance. Not all geographical subgroups are of sufficient size to make meaningful evaluations, and performance targets are defined across the whole dataset.

Subgroup	Category	n	Median DSC	Median MSD (mm)	Median RAVE (%)
Overall	–	100	0.93	0.27	3.99
Race	White/Caucasian	35	0.93	0.27	2.54
	Black/African American	24	0.93	0.30	3.65
	Hispanic/Latino	10	0.92	0.33	3.78
Ethnicity	Not Hispanic/Latino	60	0.93	0.28	3.18
	Hispanic/Latino	10	0.92	0.33	3.78
Geographic Region	US Southeast	49	0.93	0.30	2.81
	UK East of England	15	0.92	0.27	5.85
	UK South West England	15	0.94	0.22	5.51
	US Midwest	9	0.93	0.22	1.75
	US Southern	8	0.91	0.25	5.11
	US Midwest	4	0.92	0.32	10.15
PI-RADS Score	PI-RADS 1	13	0.93	0.28	3.88
	PI-RADS 2	33	0.93	0.26	4.09
	PI-RADS 3	19	0.93	0.27	5.91
	PI-RADS 4	20	0.93	0.26	3.21
	PI-RADS 5	15	0.93	0.28	3.62
Scanner Manufacturer	Siemens	56	0.93	0.29	3.50
	GE Healthcare	24	0.92	0.26	5.07
	Philips	20	0.94	0.23	5.29
Field Strength	1.5T	48	0.93	0.26	4.12
	3T	52	0.93	0.27	3.68

Performance was generally consistent across clinically relevant subgroups, including scanner types, field strengths, PI-RADS categories, and demographic groups, with all median Dice scores ≥0.91 and within predefined acceptance criteria.

The validation results demonstrate that the algorithm provides accurate and reliable prostate segmentation and volumetric measurements across a representative clinical population and imaging conditions. These results support that the device performs as intended.

Conclusion

The information provided in this submission demonstrates that Prostate Core™ is substantially equivalent to the predicate device qp-Prostate (K203582) with respect to intended use, technological characteristics, and performance.

Non-clinical verification and validation testing confirmed that the device meets its software system requirements and performs reliably within its intended operating environment. Performance evaluation using independent, multi-centre clinical imaging datasets demonstrated that the device achieves predefined acceptance criteria for segmentation accuracy and volumetric measurement, with generally consistent performance across clinically relevant subgroups, imaging conditions, and scanner types.

Although the subject device utilises a deep learning–based segmentation algorithm, this technological difference does not raise new questions of safety or effectiveness. The algorithm is a locked model, and its performance has been validated against expert radiologist reference standards using established quantitative metrics.

Based on the totality of the evidence, Prostate Core™ is as safe and effective as the predicate device and does not raise new questions of safety and effectiveness.