August 7, 2026

mediaire GmbH
Alexander Wegener
Director Regulatory Affaires and Quality Management
Ritterstrasse 16-18
Berlin, 10969
Germany

Re: K252571
Trade/Device Name: mdprostate
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 7, 2026
Received: July 7, 2026

Dear Wegener Alexander:

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,

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

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.

510(k) Number *(if known)*
K252571

Device Name
mdprostate

Indications for Use *(Describe)*
The product is intended for automatic segmentation, visualization, and volumetric quantification of the prostate on 3D MRI data (in DICOM format). The software automates the currently manual process of identifying, labeling and volumetric calculation of segmented prostate structures on 3D MRI images.
The calculated volumetric data, in addition to the image data at hand, can assist trained medical professionals in the interpretation of prostate MR studies.

Diagnosis should not be made solely based on the analysis performed using mdprostate.

The application of the software refers to patients with presumed changes in the prostate tissue and is intended to be used for men of age between 35 and 99 years.

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.

510(k) SUMMARY FOR MDPROSTATE
K252571

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. Submitter

Submitter's Name:	mediaire GmbH
Submitter's Address:	Ritterstrasse 16-18
	10969 Berlin, Germany
Date	2026-08-04

2. Contact Person

Contact Person:	Alexander Wegener
Contact Person Title:	Director Regulatory Affairs and Quality Management
Application Correspondent:	Alexander Wegener
Telephone:	+49 30 286 490 67
Email:	a.wegener@mediaire.de

3. Device Name and Classification

Product Name:	mdprostate
Trade Name	mdprostate
Classification Name:	Automated Radiological Image Processing Software
Common Name:	Medical Image Processing Software
Product Code:	QIH
CFR Section:	21 CFR 892.2050
Recommended Classification:	Class II
Classification Panel:	Radiology
510(k) Number:	K252571

4. Predicate Device

Product Name:	AI-Rad Companion Prostate MR
Propriety Trade Name	AI-Rad Companion Prostate MR
510(k) Number	K193283
Clearance Date:	July 2, 2020
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Secondary CFR Section:	21 CFR §892.1000
Device Class:	Class II
Product Code	QIH
Secondary Product Code	LNH

5. Intended Use

The product is intended for automatic segmentation, visualization, and volumetric quantification of the prostate on 3D MRI data (in DICOM format). The software automates the currently manual process of identifying, labeling and volumetric calculation of segmented prostate structures on 3D MRI images.

The calculated volumetric data, in addition to the image data at hand, can assist trained medical professionals in the interpretation of prostate MR studies.

Diagnosis should not be made solely based on the analysis performed using mdprostate.

The application of the software refers to patients with presumed changes in the prostate tissue and is intended to be used for men of age between 35 and 99 years.

6. Device Description

The product is intended for automatic segmentation, visualization and volumetric quantification of the prostate on 3D MRI data (in DICOM format). The software automates the currently manual process of identifying, labeling and volumetric calculation of segmented prostate structures on 3D MRI images.

The primary features of **mdprostate** include:

- Automatic prostate segmentation and volume estimation
- Calculation of the PSA density, based on the input of the PSA value of the patient by the user
- The user can manually add his/her evaluation of lesions (and their characteristics) in a suitable user interface. The characteristics provided include location, size, volume and ADC values and other characteristics (like PI-RADS score) for each lesion.
- Export in a suitable format for reading and archiving in PACS, as well as in a second format that can be imported by ultrasound systems (e.g. RTStruct), allowing the urologist to perform targeted MR-US fusion biopsy

7. Technological Characteristics

The subject device **mdprostate** is substantially equivalent to the predicate device with regards to software, programming languages, operating system, and fundamental technology. Mediaire made some device modifications and implemented enhancements to the existing predicate device, *AI-Rad Companion Prostate MR* (K193283).

While these enhancements and improvements offer additional image viewing and evaluation capabilities compared to the predicate device, the conclusions from all verification and validation data suggest that these modifications do not adversely affect the safety and effectiveness of the predicate device.

Table 1: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device	Comparison Results
Device Trade Name	mdprostate	AI-Rad Companion Prostate MR	
Environment of use	**mdprostate** is used by trained professionals in hospitals, imaging centers or in image processing labs.		**EQUIVALENT**
Physical characteristics	Software package Operates on off-the-shelf hardware (multiple vendors)	Software package Operates on the cloud	**ENHANCED**

Table 1: Substantial Equivalence Comparison Table			
Description	**Subject Device**	**Predicate Device**	**Comparison Results**
Device Trade Name	mdprostate	AI-Rad Companion Prostate MR	
	or on the cloud		
DICOM compatible	YES	YES	**SAME**
Design and incorporate technology	Automatic segmentation by deep machine learning	Automatic segmentation by deep machine learning	**EQUIVALENT**
Data Source	Axial T2W MRI scans and corresponding DWI and ADC maps. Can optionally evaluate DCEs.	2D TSE axial or 3D TSE / SPACE MR image data and DWI image	**EQUIVALENT**
Output	• electronic reports with information about the prostate in DICOM format • annotated DICOM images • format that can be imported by ultrasound systems (e.g. RTStruct)	• electronic reports with information about the prostate • annotated DICOM images • format that can be imported by ultrasound systems (e.g. RTStruct)	**SAME**
Testing	• Production Risk Assessment • Software Verification tests • Software validation tests	• Production Risk Assessment • Software Verification tests • Software validation tests	**SAME**

7.1. Substantial Equivalent Discussion

The technical characteristics are equivalent for the subject (mdprostate) and predicate (AI-RAD companion Prostate MR) device. Both applications use the same environment, are DICOM compatible and create similar outputs. Both devices are pure software packages and operate in the cloud. Additionally, mdprostate can be installed and operated on-premise. The technologies in both devices include deep learning algorithms. Those may differ in their configurations and/or tuning parameters, but are in general equivalent. The data used for training those algorithms differ, but both include T2-weighted and DWI MR images. Additionally, mdprostate uses the respective ADC map as an additional input.

8. Performance Testing

Non-clinical testing was performed to evaluate the functionality of **mdprostate**. This included software validation and bench testing, which were conducted to assess the device's performance claims and to support the determination of substantial equivalence to the predicate device. **mdprostate** was further tested for conformity with multiple applicable industry standards. The results of the non-clinical performance testing demonstrate that **mdprostate** complies with the FDA guidance document "Content of Premarket Submissions for Device Software Functions" (June 14, 2023), as well as with the voluntary FDA-recognized consensus standards listed in Table 2 below.

Table 2: *Voluntary* Consensus Standards

Recognition Number	Title of Standard	Reference Number and Date	Standards Development Organization
5-125	Medical devices - Application of risk management to medical devices	14971:2019	ISO
5-129	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2020	IEC
5-134	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	15223-1:2021	ISO
13-79	Medical device software - Software life cycle processes	62304:2006/A1: 2016	IEC
12-261	Information Technology –Digital Compression and coding of continuous -tone still images: Requirements and Guidelines [including: Technical Corrigendum 1 (2005)]	10918-1:1994	ISO IEC
12-363	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 (2024)	NEMA

8.1 Verification and Validation

Development of **mdprostate** was made in compliance with 21 CFR 820.30 (Design Controls). Risk management was completed in accordance with ISO 14971, Application of Risk Management to Medical Devices to assess the potential risk and harms of the device. Based on the risk analysis, appropriate verification and validation was completed and results demonstrated that the predetermined acceptance criteria were met. Software was developed and validated in accordance with ISO 62304, Software Life Cycle Processes for Medical Device Software.

Software documentation consistent for software with a basic documentation level, in accordance with the FDA guidance document "Content of Premarket Submissions for Device Software Functions" (June 14, 2023), was completed and placed in the Design History File. Software verification and validation testing demonstrated that the software performs as intended and in accordance with specifications. The potential risks of **mdprostate** have been identified and evaluated, and the risks were determined to be acceptable, or have been addressed with risk control measures.

8.2 Standalone Performance Validation

A standalone validation study was conducted to assess the segmentation performance of **mdprostate** on bi-parametric MRI. The study evaluated 97 independent imaging series from 97 unique male patients, with a strict 1:1 relationship between patients and samples (no duplicate scans, follow-ups, or repeat imaging sessions).

Reference Standard: A consensus ground truth was established for each case through a hierarchical panel of three independent board-certified radiologists who manually outlined prostate boundaries slice-by-slice; disagreements were adjudicated by a fourth senior radiologist.

Independence of Test Data: The validation dataset was subject to a strict data-lock protocol. None of the 97 cases were used at any stage of algorithm development, architecture selection, hyperparameter tuning, or model training, and the data originated from institutions independent of those that supplied the training data, ensuring an unbiased assessment of real-world generalizability.

Imaging Equipment and Protocol: Data were acquired across multiple institutions using scanners from three major manufacturers (Siemens Healthineers, GE Healthcare and Philips Healthcare), at both 1.5T and 3.0T field strengths, using high-resolution T2-weighted turbo spin-echo (TSE) axial sequences compliant with PI-RADS v2.1.

Demographics and Clinical Subgroups: The cohort was 100% male, consistent with the intended use. Participants were between 35 and 99 years of age and represented diverse ethnic groups, including White Americans, Black or African Americans, Asians, and Other (Hispanics, Native Hawaiians, Pacific Islanders, and American Indians and Alaska Natives). Performance was additionally stratified by prostate volume and by PI-RADS v2.1 category to evaluate robustness against clinically challenging confounders.

Suspected malignant lesions (PI-RADS 3–5) represent a clinically challenging confounder for segmentation algorithms, as they can distort local tissue architecture, alter signal intensity, and

obscure peripheral zone boundaries. Nevertheless, stratified analysis across all evaluated subgroups, including demographic characteristics, prostate volume, lesion status, and MRI field strength, demonstrated stable performance. Mean Dice scores ranged from 0.89 to 0.91, while mean HD95 values ranged from 3.07 to 3.84, with a variance in Dice Similarity Coefficient of less than 0.03 across all stratifications. These findings suggest no meaningful performance disparities and support the robustness of **mdprostate** across diverse patient characteristics, clinical presentations, imaging conditions, and prostate volumes.

Results: The pre-defined primary endpoint, mean Dice Similarity Coefficient (DSC), had an acceptance criterion of >0.88; mdprostate achieved a mean DSC of 0.90. As a secondary endpoint, the 95th percentile Hausdorff distance was evaluated; **mdprostate** achieved a mean 95th percentile Hausdorff distance of 3.70 mm (2.47 pixels), favorably comparable to the literature benchmark. All pre-specified performance endpoints were met.

To demonstrate that mdprostate maintains consistent segmentation accuracy and does not suffer from algorithmic degradation when applied to diverse clinical subgroups, we performed a stratified performance analysis. Table 3 reports the mean Dice Similarity Coefficient (DICE) and 95th percentile Hausdorff Distance (HD95) for each category.

Table 3: Subgroup Performance Analysis

Variable	Subgroup Category	Patients (N)	Mean DICE	Mean HD95 [mm]
Age Group (Years)	< 55	4	0.89 [0.86 | 0.91]	3.13 [2.67 | 3.57]
	55 - 70	66	0.91 [0.904 | 0.917]	3.74 [3.47 | 4.00]
	> 70	27	0.92 [0.909 | 0.927]	3.63 [3.22 | 4.19]
Ethnicity	White American	58	0.91 [0.904 | 0.918]	3.84 [3.55 | 4.16]
	Black or African American	19	0.91 [0.898 | 0.924]	3.65 [3.19 | 4.24]
	Asian American	10	0.92 [0.899 | 0.934]	3.07 [2.61 | 3.49]
	Other*	10	0.91 [0.894 | 0.925]	3.49 [3.10 | 3.98]
Scanner Manufacturer	Siemens Healthineers	49	0.91 [0.903 | 0.920]	3.80 [3.45 | 4.20]
	GE Healthcare	38	0.90 [0.882 | 0.914]	3.59 [3.26 | 3.95]

Table 3: Subgroup Performance Analysis				
Variable	Subgroup Category	Patients (N)	Mean DICE	Mean HD95 [mm]
	Philips Healthcare	10	0.92 [0.907 | 0.922]	3.58 [3.17 | 4.14]
Field Strength	1.5 Tesla	28	0.91 [0.901 | 0.921]	3.70 [3.27 | 4.16]
	3.0 Tesla	69	0.91 [0.905 | 0.918]	3.67 [3.42 | 3.98]
Prostate Volume	Small (<50 ml)	33	0.90 [0.884 | 0.907]	3.53 [3.19 | 3.92]
	Medium (50–100 ml)	43	0.92 [0.910 | 0.922]	3.74 [3.43 | 4.04]
	Large (>100 ml)	21	0.93 [0.920 | 0.937]	3.81 [3.31 | 4.61]
Disease Presence	PI-RADS 1-2 (Benign/ No Lesion)	47	0.91 [0.91 | 0.92]	3.77 [3.4 3| 4.12]
	PI-RADS 3-5 (Suspected Cancer)	50	0.91 [0.90 | 0.92]	3.59 [3.31 | 3.93]

* incl. Hispanic or Latino, Native Hawaiian or other Pacific Islander, American Indian or Alaska Native

9. Cybersecurity

mediaire has established and maintains a cybersecurity risk management process in accordance with the FDA guidance "*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*" (February 2, 2026), and the applicable statutory requirements of Section 524B of the Federal Food, Drug, and Cosmetic Act. As part of this process, which is embedded within the company's Quality Management System (QMS), mediaire implements administrative and technical controls designed to prevent unauthorized access to, unauthorized modification of, misuse of, or denial of use of the device, as well as to safeguard information stored on, accessed by, or transmitted from the device to external recipients against unauthorized use. Key elements of this process include the maintenance of a Software Bill of Materials (SBOM), a structured vulnerability monitoring and remediation procedure, and mechanisms to support the ongoing deployment of security patches and updates over the device's total product lifecycle.

10. Clinical Tests

Clinical testing was not conducted to evaluate the performance and functionality of the modifications introduced in **mdprostate.** Instead, verification and validation activities were performed to confirm that the modifications and enhancements meet their design specifications and perform as intended for their intended use. The results of these verification and validation activities support the safety and effectiveness of the subject device and the determination of substantial equivalence to the predicate device. No animal testing was performed on the subject device.

11. Safety and Effectiveness

The device labeling includes instructions for use, along with all necessary warnings and precautions, to ensure the device is used safely and effectively.

Safety is further ensured through a risk management process compliant with ISO 14971, under which potential hazards are systematically identified and mitigated through risk analysis conducted early in the design phase and maintained continuously throughout product development. Identified risks are controlled through a combination of measures implemented during software development, verification and validation testing, and product labeling.

In addition, the device is intended for use by healthcare professionals who are experienced in the post-processing and interpretation of magnetic resonance images.

12. Substantial Equivalence and Conclusion

Based on thorough verification and validation testing using applicable industry standards, mediaire GmbH concludes that **mdprostate** is substantially equivalent to *AI-Rad Companion Prostate MR* cleared under K193283.