April 29, 2026

Quantib BV
% Kim Ky
Director, Regulatory Affairs
Deephealth, Inc.
212 Elm St.
Somerville, Massachusetts 02144

Re: K253682
Trade/Device Name: DeepHealth ProstateAI
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: March 27, 2026
Received: March 27, 2026

Dear Kim Ky:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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
Magnetic Resonance and Nuclear Medicine Team
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)*
K253682

Device Name
DeepHealth ProstateAI

Indications for Use *(Describe)*
DeepHealth ProstateAI is a Computer-Aided Detection and Diagnosis (CADe/x) software device developed to aid trained physicians in the detection and characterization of prostate cancer lesions using MR imaging data in patients aged 40 years and older. DeepHealth ProstateAI analyzes T2W, ADC and DWI MR images. Combined with the MR images the software requires a binary mask containing the prostate gland segmentation. Output consists of ROI candidates including segmentations, and per ROI a classification indicating the likelihood of prostate cancer. The device is intended to assist in the detection of prostate cancer across the full range of grade groups (ISUP Grade Group ≥ 1), including clinically significant prostate cancer (ISUP Grade Group ≥ 2). Device outputs shall be input for a visualization and adaptation tool. DeepHealth ProstateAI is intended to be used as a concurrent reading aid for physicians assessing prostate MRI exams. Analysis by DeepHealth ProstateAI is not intended as a replacement for interpreting prostate abnormalities using MR image data consistent with clinical recommendations (e.g., including DCE information when available); nor should patient management decisions be made solely based on the results of DeepHealth ProstateAI.

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
Quantib BV
DeepHealth ProstateAI

K253682

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. 510(k) Submitter

Quantib BV
Westblaak 130
3012 KM Rotterdam
Tel: +31 10 841 1749

Primary Contact:
Kim Ky
Director, Regulatory Affairs
Email: regulatory@deephealth.com
Phone: 510-828-4757

Secondary Contact:
B. Nathan Hunt
Head of Quality, Regulatory, and Compliance
Email: regulatory@deephealth.com
Phone: 443-506-8911

Date prepared:
March 26, 2026

2. Device

Trade Name of Device:
DeepHealth ProstateAI

Common or Usual Name:
Radiological computer assisted detection/diagnosis software

Classification Names:
Radiological computer-assisted detection and diagnosis software (21 CFR 892.2090)

Regulation Class:
II

Product Code:
QDQ

3. Predicate Device

Trade Name of Device:
ProstatID (K212783)

Common or Usual Name:
ProstatIDTM MRI Diagnostic Aid for Prostate Cancer

Classification Names:
Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer (21 CFR 892.2090)

Regulation Class:
II

Product Code:
QDQ

4. Device Description

DeepHealth ProstateAI is a CADe/x software that uses artificial intelligence to detect and characterize prostate cancer on bi-parametric MRI (T2-weighted, ADC, DWI). The device employs convolutional neural networks to automatically detect candidate ROIs within and extending from the prostate, generate segmentations of identified regions, and classify each ROI as low, moderate, or high suspicion category. It requires prostate segmentation from a cleared device as input and outputs DICOM/NIfTI files with ROI segmentations and classifications for display in PACS viewers as color-coded overlays.

The suspicion classification system employs validated thresholds to categorize lesions into three distinct levels, with the following design targets and observed validation performance:

Suspicion category	Display color	Design target: likelihood of PCa	Observed performance (validation cohort)
Low	Green	≤20%	10% of low-suspicion confirmed as PCa
Moderate	Yellow	>20% to <80%	46% of moderate-suspicion confirmed as PCa
High	Red	≥80%	86% of high-suspicion confirmed as PCa

Design targets reflect the intended performance of the suspicion classification system at case level.

5. Indications for Use

DeepHealth ProstateAI is a Computer-Aided Detection and Diagnosis (CADe/x) software device developed to aid trained physicians in the detection and characterization of prostate cancer lesions using MR imaging data in patients aged 40 years and older. DeepHealth ProstateAI analyzes T2W, ADC and DWI MR images. Combined with the MR images the software requires a

binary mask containing the prostate gland segmentation. Output consists of ROI candidates including segmentations, and per ROI a classification indicating the likelihood of prostate cancer. The device is intended to assist in the detection of prostate cancer across the full range of grade groups (ISUP Grade Group ≥ 1), including clinically significant prostate cancer (ISUP Grade Group ≥ 2). Device outputs shall be input for a visualization and adaptation tool. DeepHealth ProstateAI is intended to be used as a concurrent reading aid for physicians assessing prostate MRI exams. Analysis by DeepHealth ProstateAI is not intended as a replacement for interpreting prostate abnormalities using MR image data consistent with clinical recommendations (e.g., including DCE information when available); nor should patient management decisions be made solely based on the results of DeepHealth ProstateAI.

User Profile

Intended users of DeepHealth ProstateAI are healthcare professionals qualified to read and interpret prostate MRI exams consistent with recommendations.

Use Environment

The DeepHealth ProstateAI device is intended for use in professional medical imaging environments, including hospital radiology departments, and outpatient imaging center. The device is not intended for use in emergency departments, intensive care units, general practitioner offices, mobile imaging units, or patient homes.

The use environment must include:

- A compatible visualization platform (PACS or advanced workstation) capable of displaying DICOM Segmentation and SC objects
- An orchestration system for workflow management and data routing
- Network infrastructure supporting secure DICOM communication
- Diagnostic-quality displays meeting medical imaging standards

The system hosting the visualization platform must meet the technical requirements specified by the platform manufacturer. Healthcare facilities must ensure users have appropriate training in prostate MRI interpretation and access to complete imaging datasets for proper clinical decision-making.

Target Population

The device is intended to be used in the population of adult males with a prostate gland undergoing MRI exams. The target population includes males aged 40 years and older with clinical indicators suggestive of possible prostate cancer, such as elevated serum PSA, abnormal digital rectal examination, family history of prostate cancer, or known genetic markers, who are referred for prostate MRI examination.

6. Predicate Device Comparison

The subject device, DeepHealth ProstateAI, is a computer-aided detection and diagnosis (CADe/x) software intended to aid trained physicians in the detection and characterization of prostate cancer lesions using MR imaging data. It analyzes T2-weighted (T2W), diffusion-

weighted (DWI), and apparent diffusion coefficient (ADC) sequences in combination with a binary prostate-gland segmentation to identify regions of interest (ROIs) and assign categorical scores (low, moderate, high) indicating the likelihood of prostate cancer. DeepHealth ProstateAI is designed for concurrent reading and is not intended as a replacement for physician interpretation or for stand-alone diagnostic use.

The predicate device, ProstatID (K212783), is a radiological computer-assisted detection (CADe) and diagnostic (CADx) software that assists radiologists in the detection, assessment, and characterization of prostate abnormalities, including cancer lesions, using MR image data. ProstatID analyzes T2W, DWI, and ADC MRI sequences to identify suspicious regions and assess their likelihood of malignancy, providing prostate and lesion volumes, likelihood scores, and a PI-RADS-suggestive exam score.

Both devices share a common intended use: to provide AI-based assistance to qualified physicians interpreting prostate MRI exams for the detection and characterization of prostate cancer lesions. Both are classified under 21 CFR 892.2090 (Product Code QDQ) as radiological CADe/x software. The observed differences in output structure (categorical levels vs. continuous PI-RADS-suggestive scores) do not alter the intended clinical purpose or raise new questions of safety or effectiveness, as demonstrated by non-clinical and clinical performance testing.

Technological Characteristics

The subject device, DeepHealth ProstateAI, and the predicate device, ProstatID (K212783), are both software-only radiological computer-aided detection and diagnosis (CADe/x) systems intended to assist qualified physicians in analyzing prostate MRI images and identifying suspicious regions. Both process T2W, DWI, and ADC MR sequences to identify regions of interest and estimate the likelihood of malignancy as part of a concurrent reading workflow.

The core technological principles are similar. Both utilize AI-based algorithms trained on biopsy-verified prostate MRI datasets. ProstatID employs Random Forest models, while DeepHealth ProstateAI uses a convolutional neural network (CNN) architecture based on a 3D Retina U-Net within the nnDetection framework. Despite differences in algorithm design, both perform automated detection and characterization of lesions suspicious for prostate cancer using multiparametric MRI data.

DeepHealth ProstateAI requires a binary prostate-gland segmentation and transformation parameters as inputs, producing ROI-level segmentations with categorical classifications (low, moderate, high) exported as DICOM Segmentation Objects or NIfTI files. ProstatID directly analyzes MRI datasets without segmentation input, generating lesion- and prostate-level malignancy likelihood scores, volumetric measurements, and PI-RADS-suggestive results as DICOM overlays and PDF reports. Both are validated for use with MRI systems from Philips, GE, and Siemens (1.5 T and 3 T) and integrate into PACS-based clinical workflows. The features are consistent with capabilities found in legally marketed reference devices and do not raise new questions of safety or effectiveness.

Target Population and User

Both devices are intended for use by trained medical professionals: radiologists or other qualified physicians experienced in interpreting prostate MRI exams. The workflow is a concurrent read, where the AI-generated results are reviewed alongside the original MR images to support detection and characterization of prostate abnormalities.

Each device is intended for use in adult male patients, aged 40 years and older, with a prostate gland undergoing prostate MRI examinations, including those with clinical indicators or family history suggestive of prostate cancer.

Output

Both devices provide AI-generated outputs designed to supplement a clinician's review by highlighting suspicious regions and indicating their likelihood of malignancy.

DeepHealth ProstateAI produces ROI-level segmentation maps with categorical classifications (low, moderate, high) for display in compatible visualization platforms. ProstatID outputs lesion- and prostate-level likelihood scores, volumetric data, and PI-RADS-suggestive exam scores as DICOM overlays and PDF reports.

Although the output format differs, both provide equivalent clinical information to the interpreting radiologist and serve as adjunctive tools for diagnostic support. Neither device is intended for stand-alone diagnostic use, and the differences in presentation do not raise new questions of safety or effectiveness.

7. Benefit-Risk Discussion

DeepHealth ProstateAI is intended to support detection of prostate cancer, which encompasses both clinically significant prostate cancer (Grade Group ≥ 2) and clinically non-significant prostate cancer (Grade Group 1). Detection of clinically significant prostate cancer is the principal clinical objective of prostate MRI, as csPCa is the disease state responsible for prostate-cancer-specific morbidity and mortality and is the threshold at which curative-intent treatment is generally indicated. Detection of Grade Group 1 disease also has clinical value, as it supports enrollment in active surveillance protocols, establishes a baseline for longitudinal monitoring of disease progression, and informs shared patient-clinician decision-making.

As a computer-aided detection device, there is a risk that the identification of lesions suspicious for cancer will not only increase the detection of true cancer but may also lead to biopsies of lesions that are ultimately determined to be non-cancer. Quantib has applied a risk management process in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to the Subject Device. The Risk Analysis for the Subject Device shows that the implemented risk controls mitigate the identified hazards. Based on this analysis, the probable benefits outweigh the probable risks, and the identified technological characteristic difference does not raise different questions of safety or effectiveness.

8. Performance Data

Quality and safety

The design and development of DeepHealth ProstateAI were conducted in accordance with applicable FDA-recognized consensus standards and guidance documents to ensure safety,

effectiveness, and regulatory compliance. The following standards and guidance documents were followed during development:

- FDA 21 CFR 820 Code of Federal Regulations Title 21 Part 820 Quality System Regulation
- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices (#5-125)
- IEC 62304:2015 – Medical Device Software – Software Life Cycles Processes (#13-79)
- IEC 62366:2020 - Medical devices - Part 1: Application of usability engineering to medical devices (#5-129)
- IEC 82304-1:2016 Health software – Part 1: General requirements for product safety
- NEMA PS3 – Digital Imaging and Communications in Medicine (DICOM) Set (#12-363)
- Content of Premarket Submissions for Device Software Functions (June, 2023)
- Guidance for Industry and FDA Staff: Software as a Medical Devices (SaMD): Clinical Evaluation (December 2017)
- FDA Guidance Medical Device Use Safety: Applying Human Factors and Usability Engineering into Medical Devices (February 2016)
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June, 2025)

All verification and validation activities, including software testing, cybersecurity evaluation, and clinical performance assessments, were conducted in accordance with these standards. Testing demonstrated that DeepHealth ProstateAI meets its specified performance claims and does not raise new questions of safety or effectiveness when compared to the predicate device.

Training dataset

The DeepHealth ProstateAI device was developed using a diverse training dataset of approximately 3,200 prostate MRI cases collected from six independent institutions across multiple geographic regions. The dataset included a broad range of imaging protocols, scanner types, and patient demographics to ensure clinical representativeness. Each case incorporated radiologist assessments and pathology-confirmed findings obtained through systematic and/or targeted biopsy, providing 883 lesion-level ground-truth labels. This diversity and quality of reference data support robust algorithm performance and generalizability across varied clinical environments and patient populations.

Performance testing

Validation of DeepHealth ProstateAI was conducted through comprehensive bench and clinical performance testing, using datasets fully independent of those used for model training. Bench testing evaluated image-processing, detection, segmentation, and classification functions on prostate MRI, with results benchmarked against expert radiologist annotations and pathology-confirmed reference standards.

Clinical performance testing comprised a multi-reader, multi-case (MRMC) reader study and an independent standalone assessment, both using a retrospectively collected dataset of 250 prostate MRI exams from multiple sites. Three cases were excluded from lesion-level analyses due to unreliable cancer localization on imaging, yielding 247 cases for the reader study primary endpoint. The reader study demonstrated a statistically significant improvement in case-level detection with AI assistance (average AUC-LROC 0.626 to 0.724, $p<0.05$). The standalone study achieved case-level AUC 0.819 and met all segmentation targets (mean DSC 0.535, mean MSD 1.641 mm); stratification showed the expected gradient across categories.

All testing met predefined acceptance criteria. Results support the safety and effectiveness of DeepHealth ProstateAI across different scanner vendors, acquisition parameters, and diverse patient populations, consistent with its intended use. No new questions of safety or effectiveness were raised when compared to the predicate device.

9. Conclusion

The data presented in this premarket notification as described above, including the verification and validation testing conducted and the risk management process followed in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to the subject device, confirm that the subject device performs comparably to the predicate device. The differences between the subject and predicate device do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Therefore, the information provided in this submission demonstrates that DeepHealth ProstateAI is substantially equivalent to the predicate device, ProstatID (K212783).