March 18, 2025

Quibim S.L.
% John J. Smith
Partner
Hogan Lovells US LLP
555 13th St NW
Washington, District of Columbia 20004

Re: K242683
Trade/Device Name: QP-Prostate® CAD
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: February 14, 2025
Received: February 14, 2025

Dear John J. Smith:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242683

Device Name
QP-Prostate® CAD

Indications for Use *(Describe)*
QP-Prostate® CAD is a Computed Aided Detection and Diagnosis (CADe/CADx) image processing software that automatically detects and identifies suspected lesions in the prostate gland based on bi-parametric prostate MRI. The software is intended to be used as a concurrent read by physicians with proper training in a clinical setting as an aid for interpreting prostate MRI studies. The results can be displayed in a variety of DICOM outputs, including identified suspected lesions marked as an overlay onto source MR images. The output can be displayed on third-party DICOM workstations and Picture Archive and Communication Systems (PACS). Patient management decisions should not be based solely on the results of QP-Prostate® CAD.

Intended patient population:
Patients above 40 years with prostate MR imaging.

Intended users:
QP-Prostate® CAD is intended to be used by physicians with proper training, including radiologists, urologists and any physician qualified to read and interpret prostate MRI consistent with ACR recommendations in the context of PI-RADS.

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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510(k) SUMMARY
Quibim's QP-Prostate® CAD
(K242683)

Submitter
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Contact Person:
- Ángel Alberich Bayarri, CEO and Founder of Quibim
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Date Prepared: March 12, 2025

Name of Device: QP-Prostate® CAD
Common or Usual Name: CAD software for lesions suspicious for clinically significant prostate cancer
Classification Name: 892.2090 radiological computer assisted detection/diagnosis software for lesions suspicious for cancer
Regulatory Class: Class II
Product Code: QDQ

Predicate Device
- Applicant: ScanMed, LLC
- Device's trade name: ProstatID™
- 510(k) number: K212783
- Product code: QDQ

Device Description
QP-Prostate® CAD is an artificial intelligence-based Computed Aided Detection and Diagnosis (CADe/CADx) image processing software. QP-Prostate® CAD uses AI-based algorithms trained with pathology data to detect suspicious lesions for clinically significant prostate cancer. The device automatically detects and identifies suspected lesions in the prostate gland based on bi-parametric prostate MRI and provides marks over regions of the images that may contain suspected lesions. There are two possible markers that are provided in different colors suggesting different levels of suspicion of clinically significant prostate cancer (moderate or high suspicion level).

The software is intended to be used as a concurrent read by physicians with proper training in a clinical setting as an aid for interpreting prostate MRI studies. The results can be displayed in a variety of DICOM outputs, including identified suspected lesions marked as an overlay onto source MR images. The output can be displayed on third-party DICOM workstations and Picture Archive and Communication Systems (PACS). Based on bi-parametric input consisting of T2W and DWI series, the analysis is run automatically, and the output in standard DICOM formats is returned to PACS.

Intended Use / Indications for Use

QP-Prostate® CAD is a Computed Aided Detection and Diagnosis (CADe/CADx) image processing software that automatically detects and identifies suspected lesions in the prostate gland based on bi-parametric prostate MRI. The software is intended to be used as a concurrent read by physicians with proper training in a clinical setting as an aid for interpreting prostate MRI studies. The results can be displayed in a variety of DICOM outputs, including identified suspected lesions marked as an overlay onto source MR images. The output can be displayed on third-party DICOM workstations and Picture Archive and Communication Systems (PACS). Patient management decisions should not be based solely on the results of QP-Prostate® CAD.

Intended patient population:

Patients above 40 years with prostate MR imaging.

Intended users:

QP-Prostate® CAD is intended to be used by physicians with proper training, including radiologists, urologists and any physician qualified to read and interpret prostate MRI consistent with ACR recommendations in the context of PI-RADS.

Comparison to predicate device

QP-Prostate® CAD and the predicate device ProstatID™ have very similar indications statements. Both are medical image processing applications intended for concurrent reading for physicians interpreting prostate MRI identifying suspected lesions and assessing likelihood for prostate cancer. Both devices generate a 3D rendition. ProstatID™ provides the regional overlay scores on a continuous scale ranging from 0-1, presented as a colorized translucent overlay, and a suggested level of suspicion or overall PI-RADS score, whereas QP-Prostate® CAD provides overlay markings around the detected suspicious lesions, in two possible colors suggesting different levels of suspicion of clinically significant prostate cancer (moderate or high).

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both devices are compatible with DICOM standard.
- Both devices use the same input sequences to run the analysis: T2-weighted and DWI acquired with specified protocols.

The following technological differences exist between the subject and predicate devices:

- Both devices are artificial intelligence-based, but they differ in algorithm methodology (e.g. ProstatID™ is based on random forest and QP-Prostate® CAD is based on Neural Networks and Machine Learning). This difference could affect its safety or effectiveness but does not raise any different questions of safety or effectiveness, because a set of verification and

validation tests (performance testing) demonstrate the safety and effectiveness of QP-Prostate® CAD.

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

Table 1: Comparison of key features of QP-Prostate® CAD (Quibim) and the predicate device ProstatID™ (Bot Image, Inc.)

Feature	Proposed device: QP-Prostate® CAD	Predicate device: ProstatID™ (K212783)	Comments
REGULATORY DATA			
Class	II	II	N/A
Regulation name	Radiological Computer Assisted Detection/Diagnosis Software	Radiological Computer Assisted Detection/Diagnosis Software	N/A
Regulation number	21 CFR 892.2090	21 CFR 892.2090	N/A
Classification Panel	Radiology	Radiology	N/A
Product Code	QDQ	QDQ	N/A
Applicant	Quibim S.L.	ScanMed, LLC.	N/A
Indications for Use			
Medical device description	QP-Prostate® CAD is a Computed Aided Detection and Diagnosis (CADe/CADx) image processing software that automatically detects and identifies suspected lesions in the prostate gland based on bi-parametric prostate MRI. The software is intended to be used as a concurrent read by clinicians with proper training in a clinical setting as an aid for interpreting prostate MRI studies. The results can be displayed in a variety of DICOM outputs, including identified suspected regions of abnormalities marked as an overlay onto source MR images. The output can be displayed on third-party DICOM workstations and Picture Archive and Communication Systems (PACS). Patient management	ProstatIDTM is a radiological computer assisted detection (CADe) and diagnostic (CADx) software device for use in a healthcare facility or hospital to assist trained radiologists in the detection, assessment, and characterization of prostate abnormalities, including cancer lesions using MR image data with the following indications for use. ProstatID analyzes T2W, DWI and ADC MRI data. ProstatID does not include DCE images in its analysis. ProstatID software is intended for use as a concurrent reading aid for physicians interpreting prostate MRI exams of patients presented for high-risk screening or diagnostic imaging, from compatible MRI systems, to identify regions suspicious for prostate cancer and assess their likelihood of malignancy. Outputs of the device include the volume of the prostate and locations, as well as the extent of suspect lesions, with	Substantially equivalent. Minor differences in outputs, exist, but both devices are CADe/x devices that characterize prostate abnormalities on MR image data. The differences do not raise different questions of safety and effectiveness.

Feature	Proposed device: QP-Prostate® CAD	Predicate device: ProstatID™ (K212783)	Comments
	decisions should not be based solely on the results of QP-Prostate® CAD.	index scores indicating the likelihood that cancer is present, as well as an exam score by way of PI-RADS interpretation suggestion. "Extent of suspect lesions" refers to both the assessment of the boundary of a particular abnormality, as well as identification of multiple abnormalities. In cases where multiple abnormalities are present, ProstatID can be used to assess each abnormality independently. Outputs of this device should be interpreted with all available MR data consistent with ACR clinical recommendations (e.g., dynamic contract enhanced images if available) in context of PI-RADs v2, and in conjunction with bi-parametric MRI acquired with either surface or endorectal MRI accessory coils from compatible MRI systems. Analysis by ProstatID is not intended as a replacement for interpreting prostate abnormalities using MR image data consistent with clinical recommendations (including DCE); nor should patient management decisions be made solely on the basis of ProstatID.	
Intended user population	QP-Prostate® CAD is intended to be used by physicians with proper training, including radiologists, urologists and any physician qualified to read and interpret prostate MRI consistent with ACR recommendations in the context of PI-RADS.	Intended users of ProstatID are physicians qualified to read and interpret prostate MRI exams consistent with ACR recommendations in the context of PI-RADS v2.	Substantially equivalent.

Feature	Proposed device: QP-Prostate® CAD	Predicate device: ProstatID™ (K212783)	Comments
Intended patient population	Patients above 40 years with prostate MR imaging.	The device is intended to be used in the population of biological adult males with a prostate gland undergoing screening or clinical MRI exams. This includes biological males with clinical indicators suggestive of possible prostate cancer or with family history of prostate cancer.	Substantially equivalent.
CHARACTERISTICS			
Clinical finding	Identification of location of suspicious lesions, with two suspicion levels of clinically significant prostate cancer, moderate or high	Extent and location of identified suspected lesions, assigned to a level of suspicion (0-1). A suggested level of suspicion or overall PI-RADS exam score.	Substantially equivalent. While minor differences exist in that QP-Prostate provides two suspicion levels, while ProstatID assigns a level of suspicion on a scale of 0-1, the intended use of the devices remain the same. Furthermore, the safety and effectiveness of QP-Prostate are supported through performance assessments and do not raise different questions of safety and effectiveness.
DICOM compatibility	DICOM-in DICOM-out	DICOM-in DICOM-out	Same
Input for analysis	T2W and DWI series, DCE is not included for analysis	T2W, DWI and ADC MRI data, DCE is not included for analysis	Substantially similar. While QP-Prostate takes a subset of the input data used in the predicate device. This difference does not raise different questions of safety and effectiveness.
Algorithm methodology	Neural Networks and Machine Learning	Random Forest	AI-based, safety and effectiveness are supported through performance assessments.
Safety	The software is intended to be used as a concurrent read by clinicians with proper training in a clinical setting as an aid for interpreting prostate MRI studies. Patient management decisions should not be based solely on the results of QP-Prostate® CAD.	ProstatID software is intended for use as a concurrent reading aid. Analysis by ProstatID is not intended as a replacement for interpreting prostate abnormalities using MR image data consistent with clinical recommendations (including DCE); nor	Same

Feature	Proposed device: QP-Prostate® CAD	Predicate device: ProstatID™ (K212783)	Comments
		should patient management decisions be made solely on the basis of ProstatID.	

Model development

QP-Prostate® CAD uses AI-based algorithms trained with biopsy outcomes as ground truth to detect suspicious lesions for csPCa (Gleason score ≥7). The training dataset included cases acquired in the US from multiple centers, with multiple magnetic fields (1.5T, 3T) and vendors (Siemens, GE Medical Systems, Philips Medical Systems). T2w and DWI sequences of these cases were used for training. The dataset contained representation of different Gleason score subgroups, was ethnically diverse, and the age ranged from 43 to 86 years. The fine-tuning of the model aimed to optimize the sensitivity and specificity at a case level for the high and moderate markers. To ensure generalizability and performance of QP-Prostate® CAD, standalone and MRMC performance testing studies have been performed with a dataset sourced from different institutions or sources in the US not part of the model training or development datasets. The description of this performance testing dataset and the results of the standalone and MRMC performance testing studies are presented below.

Performance Data

QP-Prostate® CAD software was developed according to FDA recognized consensus standards for software development. Software verification and validation was performed following V&V plans and protocols verifying that product specifications were met.

Dataset selection

The pivotal dataset included 228 cases collected retrospectively from multiple centers across the US. This dataset was completely independent from the training dataset that was acquired from different institutions. The pivotal dataset included both positive and negative cases in the same proportion. Positive cases were biopsy confirmed (Gleason score ≥ 7); negative cases were either biopsy-confirmed (Gleason score < 7) or non-biopsied with a clinical follow-up of at least one year.

Cases were acquired with multiple magnetic fields (1.5 T and 3T) and multiple vendors, and met the device's recommended acquisition parameters for the T2w and DWI sequences. The ethnicity distribution in the dataset is representative of the broader US population.

Case demographics:

Age range: 43 to 81
Age mean: 64.7

Asian: 3/228 (1.3%)
African American: 19/228 (8.3%)
White: 194/228 (85.1 %)
Other: 4/228 (1.8%)
Declined/unavailable: 8/228 (3.5%)

Hispanic: 7/228 (3.1%)

Not Hispanic: 206/228 (90.4%)
Declined/unavailable: 6/228 (6.6%)

Magnetic field strength:

1.5T: 32/228 (14.0%)
3T: 196/228 (86.0%)

Scanner vendor:

Philips Medical Systems: 46/228 (20.2 %)
GE Medical Systems: 40/228 (17.5%)
Siemens: 142/228 (62.3%)

Standalone performance assessment

For the performance evaluation, QP-Prostate® CAD outputs were compared to ground truth diagnoses derived from associated pathology reports and radiologist interpretations, at lesion-level, based on targeted biopsy locations (both positives and negatives) and negative cases without biopsy in the database (N=247).

Diagnostic accuracy of QP-Prostate® CAD was assessed with the AUC-ROC at lesion level, as well as with the sensitivity and specificity at lesion level at the operating points determined by high suspicion and moderate suspicion markers.

The results are summarized in the following table:

Table 2: Summary of the standalone performance testing for QP-Prostate® CAD.

Metric (lesion level)	Result
AUC-ROC	0.732 (95% CI: 0.668-0.791)
Sensitivity (high suspicion marker)	0.677 (95% CI: 0.593-0.761)
False Positive Rate per Case (high suspicion marker, any biopsy source)	0.417 (95% CI: 0.313-0.522)
Sensitivity (high and moderate suspicion markers)	0.795 (95% CI: 0.722-0.861)
False Positive Rate per Case (high and moderate suspicion markers, any biopsy source)	0.855 (95% CI: 0.709-0.996)

Additional subgroup analyses of patient age (≤65, >65), BMI (<25, ≥25), race/ethnicity, magnetic field (1.5T, 3T) and machine vendor (Siemens, Philips, GE) were performed. QP-Prostate® CAD's performance was consistent across all age, BMI, race/ethnicity and machine vendor subgroups. 1.5T subgroup showed a minor deviation in performance, attributed to the inherently lower image quality of 1.5T acquisitions over 3T; 3T acquisitions are preferable when available.

Clinical reader performance assessment

For the clinical reader performance assessment, a fully crossed multi-reader multi-case study was performed, where each case (N=228) was interpreted by each of the 9 readers with and without QP-Prostate® CAD output in a random-reader random-case factorial design. The clinical reader performance assessment compares the clinical reader performance in identifying clinically significant prostate cancer (Gleason score ≥ 7) when using or not using the device output.

The primary endpoint of the clinical reader performance assessment was the performance advantage of using QP-Prostate® CAD output compared to not using its output for diagnosis of csPCa lesions by clinical readers, determined by the AUC_{aided} versus $AUC_{unaided}$ at case level. The acceptance criterion was a statistically significant improvement.

The secondary endpoint was the performance advantage of using QP-Prostate® CAD output compared to not using its output for diagnosis of csPCa lesions by clinical readers, determined by sensitivity and specificity of the readers with and without QP-Prostate® CAD at case level.

Table 3: Summary of the clinical reader performance testing results for QP-Prostate® CAD.

Metric	Result
$AUC_{unaided}$	0.849 (95% CI: 0.814-0.884)
AUC_{aided}	0.868 (95% CI: 0.834-0.902)
ΔAUC (AUC_{aided}- $AUC_{unaided}$)	0.019 (95% CI: 0.001-0.038) p-value: 0.039

The test results demonstrate that QP-Prostate® CAD functioned as intended and met its primary endpoint, is acceptable for clinical use, and is as safe and effective as its predicate device, without introducing new questions of safety and efficacy.

Conclusions

QP-Prostate® CAD is as safe and effective as ProstatID™. QP-Prostate® CAD has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the QP-Prostate® CAD and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that QP-Prostate® CAD is as safe and effective as ProstatID™. Thus, QP-Prostate® CAD is substantially equivalent.