July 8, 2022

ScanMed, LLC
% Carlee Seeba
Director, Compliance And Corporate Quality
9840 S 140th Street, Suite #8
OMAHA NE 68138

Re: K212783
Trade/Device Name: ProstatID™
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: May 31, 2022
Received: June 2, 2022

Dear Carlee Seeba:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: 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)*
K212783

Device Name
ProstatID™

Indications for Use *(Describe)*

INDICATIONS FOR USE:

ProstatID™ 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 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

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.

INTENDED PATIENT POPULATION

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.

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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K212783

I. SUBMITTER

ScanMed LLC
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Phone: (402) 934-2650
Fax: (402) 778-9699

Contact Person: Randall Jones, D.E.
Date of 510(k) Submission: August 27, 2021

II. DEVICE

Name of Device: ProstatID™, Model 5SW.01 Version 2.0
Regulation name: Radiological Computer Assisted Detection and Diagnosis
Software Regulatory Number: 21 CFR 892.2090
Regulatory Classification:
Class II Product Code: QDQ
Common Name: ProstatID™ MRI Diagnostic Aid for Prostate Cancer

III. PREDICATE DEVICE

Name of Predicate: Transpara™ 1.6.0
Predicate 510(k) Number: K193229
Applicant: ScreenPoint Medical B.V.
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer Assisted Detection and Diagnosis Software
Regulatory Classification: Class II
Product Code: QDQ

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION AND ENVIRONMENT OF USE

ProstatID™ is a radiological computer assisted detection (CADe) and diagnostic (CADx) software-only device for use in a healthcare facility or hospital to assist trained radiologists in the detection, assessment, and characterization of lesions suspicious for cancer using MR image data. ProstatID 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. Deep learning and Random Forest algorithms are applied to the DICOM image set of MRI Axial Images (T2W, DWI, and ADC) of the prostate for recognition of the prostate gland, its central gland, and recognition and classifying the likelihood of malignancy of any suspicious lesions. Algorithms are trained with a large database of biopsy-proven examples of normal, benign, and cancerous tissues.

The software is not installed on the user's MRI system, PACS system, workstation, or any device other than the cloud-based servers configured as a Software as a Service (SaaS) model.

ProstatID offers the following functions which may be used during the concurrent interpretation:

1. Computer aided detection (CAD) presented as a colorized translucent overlay of the 2D axial T2 images to highlight locations where the device detected suspicious soft tissue lesions.
2. An appended post-processed T2W image set that can be viewed concurrently and linked three dimensionally via standard DICOM viewing with the original image set.
3. Decision Support is provided by the regional overlay scores on a continuous scale ranging from 0-1 with the higher scores indicating a higher level of suspicion (LOS).
4. A suggested LOS or overall PI-RADS exam score.
5. A CAD created 3D rendition of the suspect cancerous tissue within the transparent 3D prostate gland.
6. A .PDF report summarizing the software results with 2D and 3D images indicating suspect cancerous regions if detected.

Results of ProstatID are computed in a processing server which accepts prostate MRI exams in DICOM format as input, identifies the required axial image sets and processes them, deletes all others, and sends the output to append to the unique patient study destination using the DICOM protocol and format for post-processed images and reports. Use of the device is supported for images from the following MRI systems: Philips 1.5T, GE 1.5T, GE 3.0T, Philips 3.0T and Siemens 3.0T. Common destinations are medical workstations, PACS and RIS that utilize DICOM image transfer. ProstatID is offered as a virtual or SaaS application and runs on dedicated servers. Implementation requires secure VPN connection between client and SaaS server.

V. INDICATIONS FOR USE

ProstatID™ 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.

Output of the device includes the volume of the prostate and locations, as well as the extent of suspect lesions, with 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 based on ProstatID.

Intended user population
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.

Intended patient population
The device is intended to be used in the population of biological males with a prostate gland undergoing screening or clinical MRI exams. This includes biological males of all ages with clinical indicators suggestive of possible prostate cancer or with family history of prostate cancer.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indications for Use statement for ProstatID (Section V) is similar but not identical to the predicate device; however, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the detection, assessment, and characterization of lesions suspicious of cancer by use of artificial intelligence algorithms synthesizing a single value index or score; whereby the algorithms have been trained with a large database of biopsy-proven examples of normal, benign, and cancerous tissues.

While the predicate device assists radiologists in the detection, assessment and characterization of breast abnormalities using Mammographic image data, ProstatID assists radiologists in the detection, assessment and characterization of prostate abnormalities using MR image data.

A technical comparison of the predicate device and ProstatID is provided in Table 1 below.

Table 1: Technical comparison between the predicate device and ProstatID

Technological Characteristic	Transpara	ProstatID	Rationale of no Change to Safety and Effectiveness
Device is utilized to assist radiologists in assessment of breast abnormalities using full-field digital mammography exams and digital breast tomosynthesis exam.	Yes	No	ProstatID is utilized to assist radiologists in assessment of prostate abnormalities using MR image data. Safety and effectiveness are supported through performance assessments.
Software automatically registers images.	Yes	Yes	Same
Detects and marks locations suspicious of lesions.	Yes	Yes	Same with different marking
Decision Support by region scores with higher scores indicating a higher level of suspicion	Yes	Yes	Similar with different scale
Features are synthesized by an artificial intelligence algorithm into a single exam score.	Yes	Yes	Same.
Device Neural Net was trained on a database of reference normal tissues and abnormalities with known ground truth.	Yes	No	ProstatID was trained on a database with reference normal tissues and abnormalities with known ground truths; however, the detection algorithm uses Random Forest vs. Neural Nets
May be used as an image viewer.	Yes	No	ProstatID does not include a standalone graphical user interface. Rather, ProstatID outputs are in DICOM format and may be viewed on DICOM- compliant image viewers.

VII. PERFORMANCE DATA

1. **Biocompatibility Testing: Not Applicable**
2. **Shelf Life/Sterility: Not Applicable**
3. **Electrical Safety and Electromagnetic Compatibility: Not Applicable**
4. **Magnetic Resonance Compatibility: Not Applicable**
5. **Software Verification and Validation Testing**

Verification and validation tests of ProstatID were performed to confirm the design requirements of the software. Design requirements, hazard mitigation requirements, and software tests were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11,

2005. It was determined that the Level of Concern was "Moderate."

6. **Standalone Performance Assessment**

A standalone performance assessment was conducted on ProstatID in order to test the detection and assessment accuracy of the algorithm as recommended by FDA's Guidance for Industry and FDA Staff, "Computer Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions," dated July 3, 2012. The assessment was conducted using a mix of 150 retrospective data (the same as used in the clinical study) set aside prior to algorithm development and training. This data represents a sampling of data from various MRI platforms, locations, and physician groups, and contains accurate 3-dimensional locations of targeted biopsy points with a mix of positive and negative biopsies that represents the approximate percentage of patients presenting with cancer as the larger population sampled.

This study consisted of three tests to indicate how well the device would perform in terms of detection and diagnosis or classification of the probability of cancer by comparing the algorithm output to the ground truth biopsy data. These tests are summarized below.

i. – Diagnostic Accuracy (Lesion-based ROC Analysis)
Diagnostic performance was assessed using the area under the curve (AUC) of the receiver operating characteristic (ROC) curve when comparing the value of the ProstatID index at each of the 220 biopsy locations (90 cancerous, 130 non-cancerous) and 150 cases (44 Normal; hence no biopsies) compared to the true positive/true negative status of the biopsy result.

ii.- Standalone Detection Performance (FROC Analysis)
The performance of the algorithm to detect true positives was assessed using the free-response ROC (FROC) curve. The FROC analysis is a method for evaluating the performance of both detection and classification in a free-response system. In this case, the free-response system is the localization and classification of cancerous lesions in prostate MRI. A single case may have none, one, or multiple cancerous lesions. The FROC curve is a plot of sensitivity versus false positives per patient. FROC analysis needs two main components for evaluation: a designation of "detection" and a measure of "confidence". For ProstatID, the level of confidence at a particular point is the value of the ProstatID index at that point. Detections associated with a positive biopsy were classified as true positives. Detections that did not match a positive biopsy (i.e., a negative biopsy or a detection in normal tissue) were classified as false positives.

iii. - Detection Performance (AFROC Analysis): CAD vs. Readers
The performance of the algorithm to detect true positives was assessed using an alternative free-response ROC (AFROC) curve; and later compared to the average AFROC curve of the physicians participating in the clinical assessment (Section 7). The AFROC method of plotting is used so that both curves are between zero and one on the x-axis and compares the sensitivity to false positive fraction. Detections by ProstatID were matched to the truth table and their index value recorded. Detections that did not match the truth table were recorded as false positives.

RESULTS

Diagnostic Accuracy (Lesion-level ROC Analysis)
The standalone ROC performance of ProstatID yielded an AUC of 0.710, showing that ProstatID has good performance on its own. The reader-averaged AUC from the MRMC experiment was comparatively 0.629 when not using ProstatID.

Standalone Detection Accuracy (FROC Analysis)
ProstatID demonstrated a detection performance with a sensitivity of 80% at a rate of one false positive per patient, increasing to 98% at the rate of 3 false positives per patient.

Standalone Detection Accuracy (AFROC): CAD vs. Readers
AFROC analysis utilizes the weighted alternate FROC (wAFROC) metric (θ), which is a measure of detection performance and is analogous to the area under the ROC curve. When compared to the readers' unassisted read, ProstatID performed better at detecting and rating cancerous lesions ($\Delta\theta = +0.169$). This difference in performance is statistically significant at the 5% level ($p = 0.029$).

7. **Clinical Performance Assessment and Results**
A clinical performance assessment was designed to test if the use of ProstatID led to a statistically significant improvement in performance over the current standard of care by its intended users. The assessment utilized a retrospective study design and included 150 patient cases, of which 130 had complete follow-up and 20 were MRI-negative cases without complete follow-up. A group of 9 trained physicians that were blinded to the results interpreted each case independently in two separate reads: first without ProstatID, and second with ProstatID. The impact of ProstatID on reader performance was estimated using a multiple reader, multiple case (MRMC) analysis, with both readers and cases considered as random variables.

Primary Endpoint
The primary endpoint of the clinical performance assessment was the expected difference in the AUC of the ROC curve between the first read (without ProstatID) and the second read (with ProstatID).

The average AUCs for the unassisted read (without CAD) and the read with ProstatID (with CAD) are shown in Figure 1 and in Table 2 for the 130 cases with complete follow-up. The estimated improvement in the area under the ROC curve for rating true positive patients was 0.042. This result is statistically significant at the level $\alpha=0.05$.

Figure 1: ROC curves averaged across readers for the unassisted read (without CAD) and the read with ProstatID (with CAD)

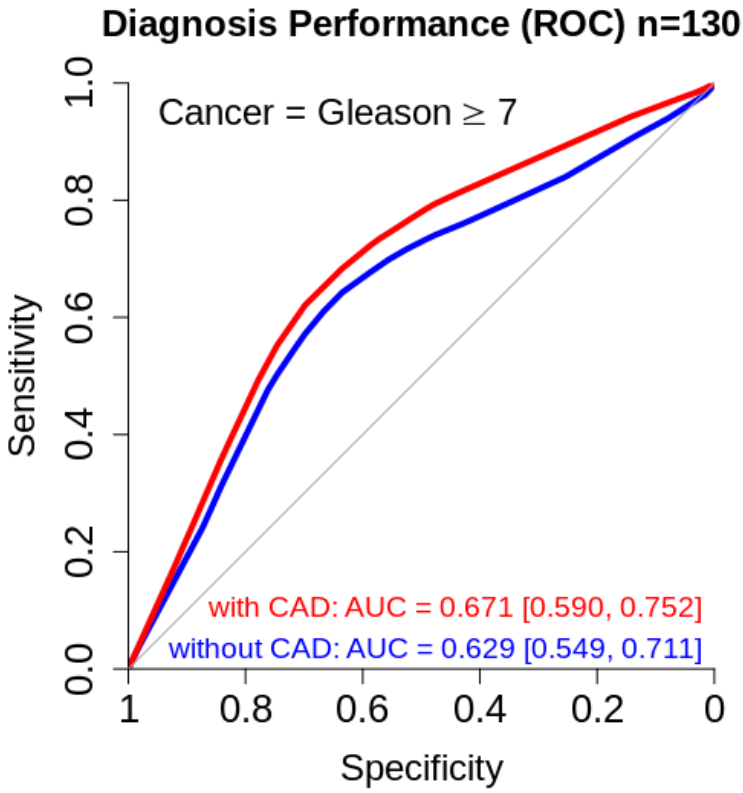

Table 2: MRMC estimate of summary modality-specific trapezoidal area under the ROC curve (AUC).

Modality-Specific AUC	**AUC**	**95% CI**	**p-value**
$AUC_{1st\ Read}$ (without CAD)	0.629	[0.549, 0.711]	-
$AUC_{2nd\ Read}$ (with CAD)	0.671	[0.590, 0.752]	-
ΔAUC = $AUC_{2nd\ Read}$ - $AUC_{1st\ Read}$	+0.042	[0.005, 0.080]	0.0291

An analysis of the effect of false negatives on an experiment with the full 150-case set was also performed. Based on a separate experiment involving the consensus opinion of a panel of experts, it was estimated that 0 to 3 cases out of the 20 MRI-negative cases without complete follow-up were potentially false negatives (negative predictive value of expert panel being 92% [85%, 98%]). The analysis of false negatives utilized simulation and bootstrapping to estimate the distribution of the *t*-statistic for a fixed false omission rate. The results of the analysis showed that the p-value of the experiment remains below 0.05 for negative predictive values as low as 80% or approximately 4 false negatives out of 20 cases.

Secondary Endpoint: Detection Accuracy (FROC Analysis)

The secondary endpoint was to demonstrate the detection and classification ability of the software via improving the FROC curves of typical physicians interpreting prostate MRI using the localization method described above. The FROC curve's analogue to the ROC AUC is the weighted alternative FROC (wAFROC) figure of merit, which more appropriately measures both the detection (location) and classification performance in the radiological study. This measurement also reflects the sensitivity versus the number of biopsies; hence is a measurement of unnecessary biopsies or those ordered for non- cancerous lesions.

The overall average free-response ROC curves and performance metrics for the unassisted read (without CAD) and the read with ProstatID (with CAD) are shown in Figure 2 and Table 3 for the 130 cases with complete follow-up. The use of ProstatID yielded an increase in the figure of merit performance of 0.043. This increase is statistically significant at the level α=0.05.

Figure 2: Free-response ROC (FROC) curves averaged over readers for detecting cancerous lesions for the unassisted read (without CAD) and the read with ProstatID (with CAD). The weighted alternative FROC (wAFROC) figure of merit (θ) is listed for each method.

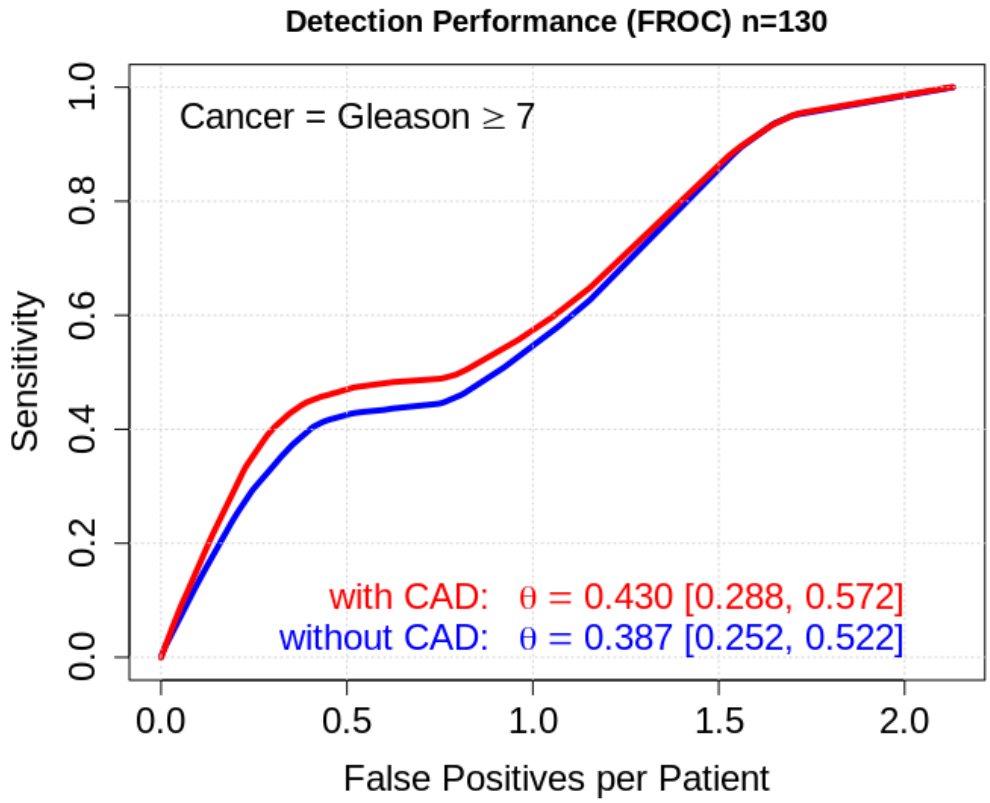

Table 3: Free-response ROC (FROC) results. The weighted alternative FROC (wAFROC) figure of merit (θ) is reported for each method. P-values are reported for the test that the change in reader-averaged performance between methods (**Δ**θ) is zero.

Modality	θ **[95% CI]**	**p-value (Δ**θ = 0**)**
without CAD	0.387 [0.252, 0.522]	0.034
with CAD	0.430 [0.288, 0.572]	

Additional Analyses Summary

Additional analyses were also conducted and are summarized here:

- **Reduction of Unnecessary Biopsies**: To test if the use of ProstatID would reduce the decisions to biopsy a benign outcome, a mixed effects analysis was used. Fixed effects were the true positive state (outcome) and the use of ProstatID (modality). Random intercepts were included for each reader and each patient case. The response variable to predict was the decision to biopsy. Results showed that the model accuracy was 84.3%. The readers were 1.06 times more likely to biopsy a benign lesion when not using ProstatID, however, the interaction of using ProstatID was not considered significant (p = 0.590). The readers were 1.30 times more likely to biopsy a cancerous lesion when using ProstatID, however, the interaction of using ProstatID was only marginally significant (p = 0.058).
- **Individual Reader ROC Curves**: Individual reader ROC curves were produced and analyzed for each reader for each modality. These curves illustrated what has been extensively published: that inter-reader variability is significant and remains so with prostate MRI.
- **Correlation of Age and PSA to PCa**: To test if patient age and prostate-specific antigen (PSA) levels were predictive of prostate cancer in the set of patients in the clinical study, age and PSA level were used as explanatory variables in a logistic regression model. Patient age at time of imaging was known for all patients, however, PSA levels were known for only 112 out of the 150 patients (74.7%). Results showed that age was significantly correlated with prostate cancer (p = 0.043) and PSA level was only marginally correlated with prostate cancer (p = 0.065). The logistic regression model was not a good predictor of outcome (accuracy 60.7%).

8. **Summary**

ProstatID met all pre-defined endpoints in the Clinical Performance Assessment. The results of the Standalone Performance Assessment and the Clinical Performance Assessment provide evidence for the safety and effectiveness of ProstatID when used in accordance with the indications for use. This safety and effectiveness profile is similar to that of the predicate device.

VIII. CONCLUSIONS

The data presented in this 510(k) includes all required information to support the review of ProstatID by the FDA for a determination of substantial equivalence with the predicate device. The software verification and validation demonstrate that ProstatID should perform as intended in its specified use conditions. Standalone tests and a clinical reader study provide evidence for the safety and effectiveness of ProstatID and demonstrate that ProstatID performs comparably to the legally marketed predicate device.