



May 14, 2026

Subtle Medical, Inc.
Adam Heroux
Consultant
883 Santa Cruz Ave.
Suite 205
Menlo Park, California 94025

Re: K254013

Trade/Device Name: SubtleHD-PET (1.x)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 13, 2026
Received: April 13, 2026

Dear Adam Heroux:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

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

Enclosure

Indications for Use

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

K254013

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Please provide the device trade name(s).

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SubtleHD-PET (1.x)

Please provide your Indications for Use below.

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SubtleHD-PET is an image processing software intended for noise reduction of PET images (including PET/CT and PET/MR) obtained with any kind of radiotracer (e.g. 18F-FDG).

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

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

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SubtleHD-PET 510(k) Summary

K254013

Table 1. Contact Details and Device Name

Date Summary Prepared:	13 April 2026
Contact Details:	
Company Name:	Subtle Medical, Inc.
Company Address:	883 Santa Cruz Ave, Suite 205 Menlo Park, CA 94025 United States
Applicant Name:	Mr Ajit Shankaranarayanan
Application Telephone:	650-448-4285
Applicant Email:	ajit@subtlemedical.com
Device Name:	
Device Trade Name	SubtleHD-PET (1.x)
Common Name:	Medical image management and processing system
Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ
Device Class:	Class II
Legally Marketed Predicate Devices:	Primary Predicate #: K213140 Primary Predicate Name: Claritas iPET Primary Predicate Legal Manufacturer: Claritas Healthtech Pte, Ltd. Secondary Predicate #: K211964 Secondary Predicate Name: SubtlePET Secondary Predicate Legal Manufacturer: Subtle Medical, Inc.

Device Description Summary

SubtleHD-PET is an AI/ML radiological image processing Software as a Medical Device (SaMD). SubtleHD-PET uses deep learning algorithms to enhance medical images acquired by PET scanners to reduce image noise. As it only processes images for the end user, the device has no user interface. SubtleHD-PET is intended to be operated by radiologists, nuclear medicine physicians, and technologists at an imaging center, clinic, or hospital through an Medical Device Data System (MDDS) to prepare and send input DICOM images and retrieve

output DICOM images. SubtleHD-PET does not have a user interface or interact with the PET scanner. The SubtleHD-PET software can be used with PET images acquired as part of standard-of-care and accelerated PET exams as the input. SubtleHD-PET has two models: PET/CT model which takes the PET and CT DICOMs (from PET/CT) as the input and PET-only model which takes the PET DICOMs (from PET/MR or PET/CT) only as the input. The outputs are the corresponding images with enhanced image quality. Original DICOM images are passed onto the SubtleHD-PET software as an input argument and the enhanced images are saved in the designated location prescribed when running the SubtleHD-PET software.

The SubtleHD-PET software implements an image enhancement algorithm using a convolutional neural network. Input images are enhanced by running through the CNN that consists of cascaded layers to perform numerical operations, including convolutional filtering, linear combination, and nonlinearity operations.

Intended Use / Indications for Use

SubtleHD-PET is an image processing software intended for noise reduction of PET images (including PET/CT and PET/MR) obtained with any kind of radiotracer (e.g. 18F-FDG).

Intended Use / Indications for Use Comparison

SubtleHD-PET and its predicates are all intended to denoise PET images of various input protocols, imaging scanners, and radiotracers.

Technological Comparison

SubtleHD-PET and its predicates are all used for image enhancement. They operate on DICOM files, enhance the images, and send the enhanced images to any desired destination. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Both subject and predicate devices use convolutional neural network based filtering. Original images are enhanced by running through a cascade of filter banks, where thresholding and scaling operations are applied. The software performs noise reduction. Additional pre- and post-processing is applied to configure desired perceived image quality. The following table provides a detailed description of the technological characteristics of subject and predicate devices.

SubtleHD-PET v1.x is classified as Class II with product code LLZ through the FDA using Claritas iPET and SubtlePET as predicates. Below is a preliminary comparison of SubtleHD-PET and the predicates.

Table 2. Comparison of Technological Characteristics

Comparison	SubtleHD-PET v1.x (Subject Device)	Claritas iPET (Predicate) (K213140)	SubtlePET v2.x (Predicate) (K211964)	Noted Differences
Indications for Use	SubtleHD-PET is an image processing software intended for noise reduction of PET images (including PET/CT and PET/MR) obtained with any kind of radiotracer (e.g. fluorodeoxyglucose (FDG)).	Claritas iPET is an image processing software intended for use by radiologists and nuclear medicine physicians for noise reduction, sharpening, and resolution improvement of PET images (including PET/CT and PET/MRI) obtained with any kind of radionuclides, e.g. fluorodeoxyglucose (FDG). Enhanced images will be saved in DICOM files and exist in conjunction with original images.	SubtlePET is an image processing software intended for use by radiologists and nuclear medicine physicians for transfer, storage, and noise reduction of fluorodeoxyglucose (FDG), amyloid, 18F-DOPA, 18F-DCFPyL, Ga-68 Dotatate, and Ga-68 PSMA radiotracer PET images.	Claritas iPET has sharpening and resolution enhancement. SubtleHD-PET v1.x claims any radiotracer, similar to Claritas iPET rather than listing the radiotracers like SubtlePET v2.x. Subject and predicate devices are both image enhancement algorithms for denoising. Substantially equivalent.
Intended Use	Image enhancement system which is an image processing software for image enhancement of PET images including PET/CT and PET/MRI.	Same	Same	Same
Workflow	The software operates on DICOM files, enhances the images, and sends the enhanced images to any desired destination with an AE Title (e.g., PACS, PET device, workstation, and more). Enhanced images coexist with the original images.	Same in case of the PACS integrated version. The stand-alone version can input the slices of the PET, MR or CT scans as DICOM files, interactively visualizes the input and the output data, and saves the enhanced volume in DICOM files.	Same	Claritas iPET has a user interface for their stand-alone version. Substantially equivalent.
Product Code	LLZ	LLZ	KPS, LLZ	Same
Physical Characteristics	Software package that operates on off-the-shelf hardware	Software package that operates on a virtual machine (VM) or deployed on a local computer.	Software package that operates on off-the-shelf hardware	Same
Intended User	Radiologists and nuclear medicine physicians	Same	Same	Same

Comparison	SubtleHD-PET v1.x (Subject Device)	Claritas iPET (Predicate) (K213140)	SubtlePET v2.x (Predicate) (K211964)	Noted Differences
Intended Location	Medical facility (hospitals, clinics, imaging center, etc.)	Same in case of the PACS integrated version. The stand-alone version runs on the client computer.	Medical facility (hospitals, clinics, imaging center, etc.)	Same
Modalities	Multi-modality; specifically processes PET, PET/CT and PET/MR images	Same	Same	Same
Input(s)	Requires either (1) PET and CT DICOM series from PET/CT scanner, (2) PET DICOM series from only PET or PET/MR scanner	Processes PET DICOM from either PET/MR or PET/CT.	Processes PET DICOM from either PET/MR or PET/CT.	SubtlePET only processed the PET DICOM series from PET/CT scanner. SubtleHD-PET uses input from the PET and CT DICOM series to process from a PET/CT scanner. Substantially equivalent.
Operating System / Computer	Linux	Windows/Linux	Linux	Same
Rx or OTC	Rx	Same	Same	Same
User Interface	None	None - when integrated into existing PACS workstations, viewed on existing PACS workstation. A user interface for stand-alone version visualizing 2D slices and 3D rendering for demo and research purposes.	None	Claritas iPET has a user interface for their stand-alone version. Substantially equivalent.
DICOM Standard Compliance	The software processes DICOM compliant image data	Same	Same	Same

Comparison	SubtleHD-PET v1.x (Subject Device)	Claritas iPET (Predicate) (K213140)	SubtlePET v2.x (Predicate) (K211964)	Noted Differences
Image Enhancement Algorithm Description	The software employs 2 different convolutional neural network models in a pixel's neighborhood to compute the value for each pixel. One model uses both PET and CT as model inputs if PET and CT images are available. The other model uses PET as the only model input if CT image is not available. The software predicts the noise components and structural components in PET images. The software separates these components, which enhances the structure while simultaneously reducing the noise.	The image enhancement algorithm is a modification of the non-local means algorithm where the filtering weights can be obtained from higher resolution and lower noise voxel arrays obtained with other modalities, i.e. CT or MR. The resolution of the target is at least the maximum of the combined modalities, but may be higher.	The software employs a convolutional neural network-based method in a pixel's neighborhood to generate the value for each pixel. Using a residual learning approach, the software predicts the noise components and structural components. The software separates these components, which enhances the structure while simultaneously reducing the noise	Subject and predicate devices use image enhancement algorithms as their core technology. Substantially equivalent.
Model Architecture	Two Models: PET-CT model, PET-only model	Unknown	One Model: PET model	SubtleHD-PET has two models while SubtlePET only had one model. Subject and predicate devices use PET DICOMS as the model architecture. Substantially equivalent.

Predetermined Change Control Plan (PCCP)

SubtleHD-PET has a Predetermined Change Control Plan (PCCP), which details planned device modifications, the associated methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications. In general, Subtle Medical utilizes PCCPs for planned modifications that aim to improve customer satisfaction with respect to perceived image quality, generalizability, and flexibility of the product.

The SubtleHD-PET PCCP plans for changes to add additional denoising mix factor levels to allow for configuration that best fits each user's perceived image quality preferences. Additionally, SubtleHD-PET plans for changes to add additional data to the performance and training datasets for generalizability. This includes additional ages, scanner vendors/models, anatomies, detector types, and radiotracers.

These modifications shall be performed as a part of Subtle Medical's Design Change Control process in a Quality Management System that is ISO 13485:2016 and MDSAP certified. It shall be accompanied by a software version-specific Customer Release Notes describing the change along with software version-specific Instructions for Use (IFU). The updated labeling shall be delivered to users by Subtle Medical customer success personnel.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Subtle Medical conducted the following performance testing:

- Software Verification and Validation testing (unit, integration, and system testing) to demonstrate that software requirements are implemented. These tests passed.
- Performance Validation testing utilizing retrospective clinical data to demonstrate the software enhanced image quality in PET images via a reduction of noise. These tests passed.
- A Reader Study utilizing retrospective clinical data to demonstrate the software enhanced image quality in PET images via a reduction of noise. These tests passed.

Performance Validation & Reader Study Dataset Characteristics:

To represent the patient population and use of PET in the field, the SubtleHD-PET performance and reader study validation test dataset consists of:

- Brain and Whole Body anatomical regions.
 - PET Only Model: Brain (29%), Whole Body (71%)
 - PET/CT Model: Brain (20%), Whole Body (80%)
- BGO, LBS, LSO, LYSO, and SiPM detector types.
- 18F-Choline, 18F-DCFPyL, 18F-DOPA, 18F-FDG, 18F-Florbetaben, 18F-Florbetapir, 68Ga-Dotatate, 18F-Flutemetamol, and 68Ga-PSMA radiotracers.
- For 18F-FDG, at least 20% of the dataset has a high Body Mass Index (BMI) (≥ 30).
- GE, Philips, Siemens, and United Imaging Healthcare imaging scanner vendors.
 - PET Only Model: GE (54%), Philips (7%), Siemens (24%), and United Imaging Healthcare (15%)
 - PET/CT Model: GE (54%), Philips (7%), Siemens (14%), and United Imaging Healthcare (25%)
- Pediatric and Adult subject ages (ranging from 2 to 88 years old).
 - PET Only Model: 87% Adult, 13% Pediatric
 - PET/CT Model: 85% Adult, 15% Pediatric
- Subject sex.
 - PET Only Model: 43% Male
 - PET/CT Model: 48% Male
- Standard-of-care PET data and Low-count PET data from accelerated scans (25%-90% acceleration equating to 10%-75% count PET data).

Various clinical conditions are present in the performance dataset, as per reports accompanying the images from the sources, including: Cancer Follow-Up, Cardiomyopathy, Epilepsy, H&N

Cancer, Lymphoma, and Seizure. This selection criteria represents a well characterized clinically-relevant reference dataset.

To show the performance of the device was not hindered by site variability, in the validation dataset, data was selected from sources not included in the training dataset. The majority of performance data comes from sources in the United States. Independence between the training and test datasets was ensured by using non-overlapping datasets, with no shared subjects, studies, or images between training and testing.

Even though all the primary endpoints metrics for performance have passed, analysis of the device's performance across the various subgroups in the performance dataset showed slight variations. As an example, Figure 1 below shows the differences in average PSNR and SNR improvements between the different subgroups of the PET-only model results. While all the subgroups demonstrate significant improvements from SubtleHD-PET processing, subgroups like Brain, 18F-Flutemetamol & 18F-DOPA (for average PSNR) and 68-Ga-PSMA & 18F-DOPA (for SNR increase) showed lesser performance gains. Therefore, we advise the users to expect slight performance differences based on various confounding factors.

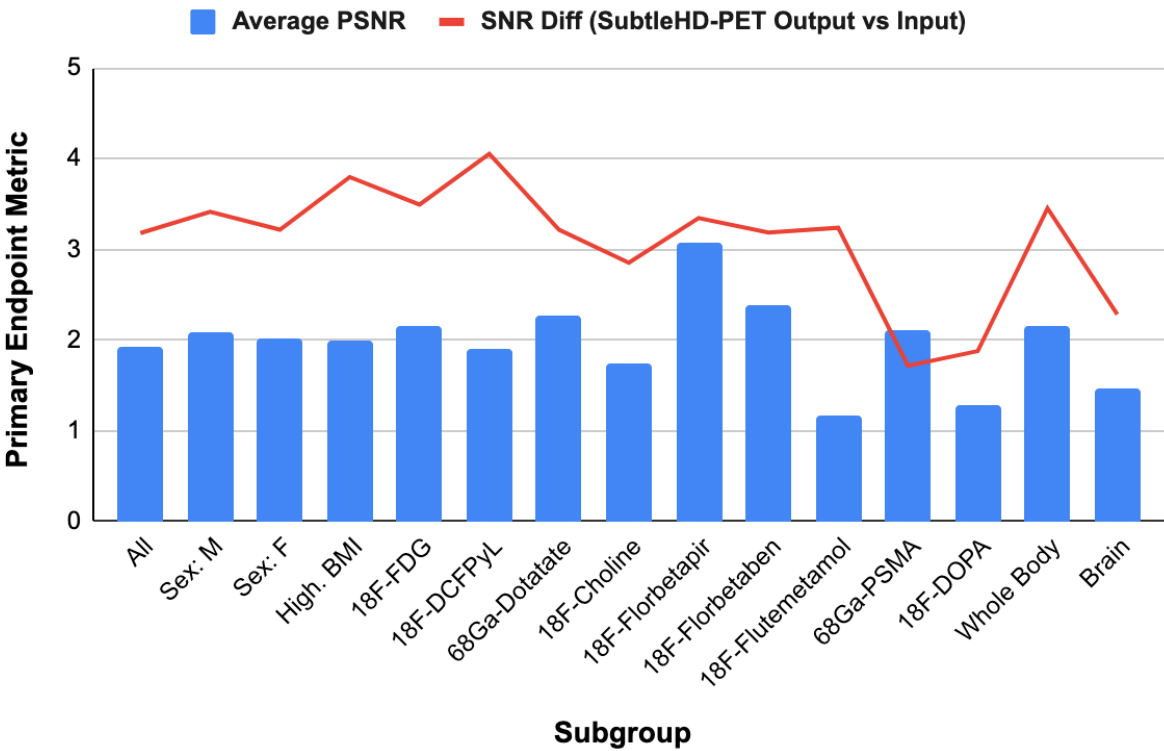


Figure 1: Plot showing the device’s performance differences in average PSNR and SNR improvements between the different subgroups of the PET-only model results.

We observed statistically significant differences in performance metrics (PSNR, SNR, RMSE, SSIM) between the "Training Site" and "Not Training Site" subgroups, but these differences are reduced and become non-significant when we balance the datasets of the two cohorts. Therefore, we contend that this difference is not a result of model bias toward specific clinical sites, but rather a reflection of the imbalance in anatomy and radiotracer types between the two cohorts.

Various reconstruction methods are present in the performance dataset, as per the metadata accompanying the images from the sources, including: BLOB-OS-TF, FORE - OSEM 3D, OSEM 2D, OSEM 3D, OSEM 3D + PSF, OSEM 3D + PSF + TOF, OSEM 3D + TOF, Q.Clear, VPFX, VPFX + PSF, VPHD and VPHD + PSF. While some reconstruction methods receive greater benefits from SubtleHD-PET processing, all 12 reconstruction methods showed a significant improvement across PSNR, RMSE, SSIM, and SNR. In the χ^2 analysis, reduced performance was observed with VPFX + PSF reconstruction. Therefore, we suggest caution while using SubtleHD-PET for VPFX+PSF.

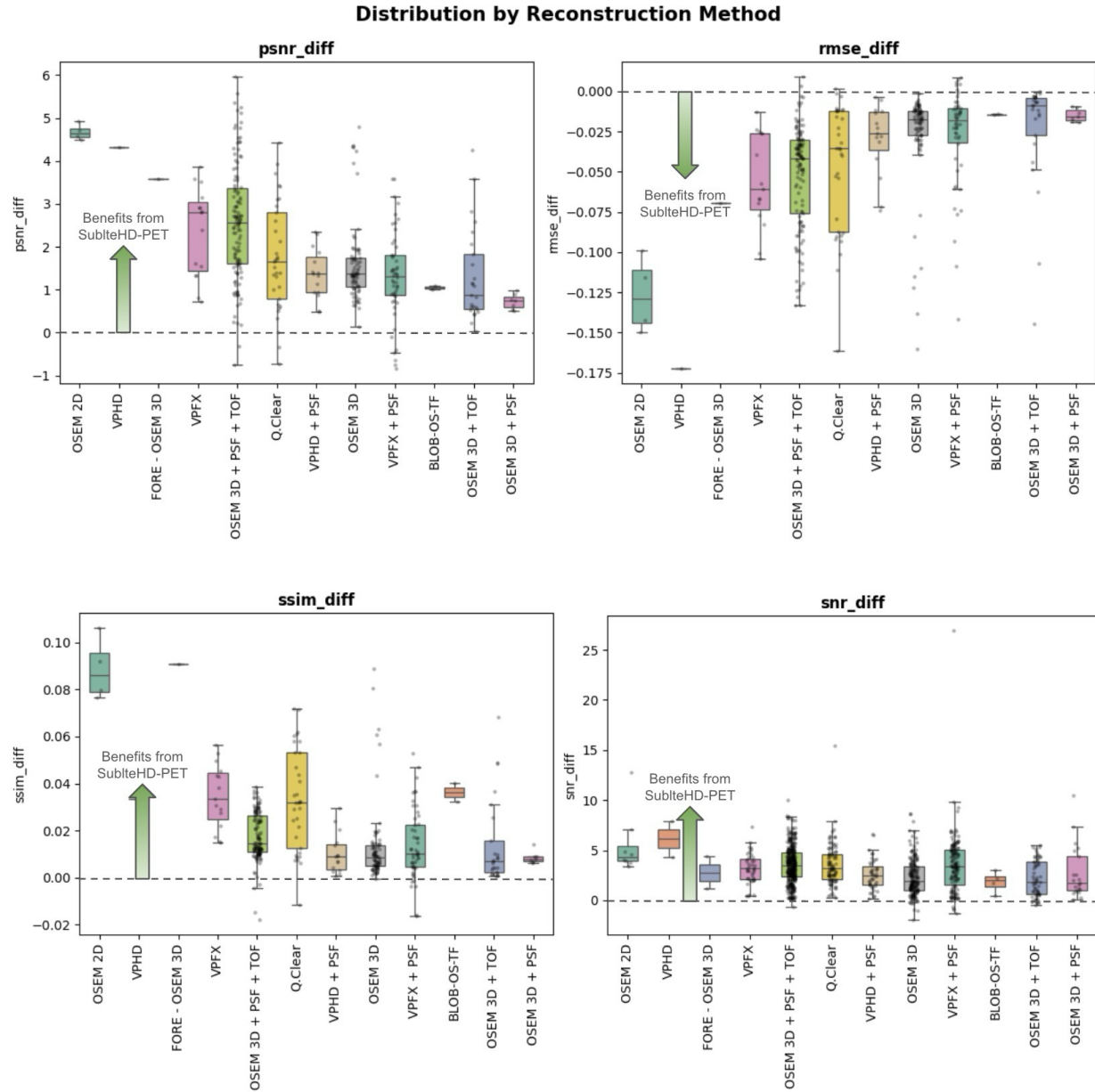


Figure 1. Box plot of device performance metrics with respect to reconstruction method. Across all reconstruction methods, quantitative metrics showed a significant improvement after processing with SubtleHD-PET.

Performance Validation:

This study utilized retrospectively acquired human data acquired as part of research studies or clinical exams from various institutions. For each dataset, four slices were selected from the upper quartile of slices, 2nd quartile, 3rd quartile, and lowest quartile by a Subtle Medical employee with an MD and/or a PhD in a clinically-relevant field for the calculation of PSNR, RMSE, and SSIM. For the calculation of SUVmax and SNR, 2 rectangular ROIs are drawn in an area with focal uptake (lesion) and background regions, respectively, by a Subtle Medical

employee with an MD and/or a PhD in a clinically-relevant field. In total 203 *studies were used to validate the PET-only model and 122 studies used to validate the PET/CT model acceptance criteria in Table 3 at three different mix factors (low, default, high).*

The following are the endpoints, acceptance criteria, results, and conclusions from the SubtleHD-PET:

Table 3. Performance Validation Summary

Endpoint	Acceptance Criteria	Result /Conclusion
Denoising (Peak Signal-to-Noise Ratio) Primary Endpoint	The average increase in PSNR is ≥ 1 dB and the PSNR increase is significant at the $p < 0.05$ level based on two-tailed paired t-test.	PASS: The average increase in PSNR was ≥ 1 dB. PSNR increase was significant at the $p < 0.05$ level based on two-tailed paired t-test.
Denoising (Peak Signal-to-Noise Ratio) Exploratory Endpoint	Report the range and average PSNR improvement.	Average PSNR improvement for the PET-only model in the default configuration is 1.935 dB, with a range of up to 5.964 dB. Average PSNR improvement for the PET/CT model in the default configuration is 1.215 dB, with a range of up to 6.065 dB.
Denoising (Signal-to-Noise Ratio) Primary Endpoint	SNR increase is significant at the $p < 0.05$ level based on one-tailed paired t-test.	PASS: The average increase in SNR was significant at the $p < 0.05$ level based on one-tailed paired t-test.
Denoising (Signal-to-Noise Ratio) Exploratory Endpoint	Report the range and average SNR improvement.	Average SNR improvement for the PET-only model in the default configuration is 3.179 dB, with a range of up to 26.938 dB. Average SNR improvement for the PET/CT model in the default configuration is 4.590 dB, with a range of up to 29.876 dB.

Endpoint	Acceptance Criteria	Result /Conclusion
Denoising (Root Mean Square Error) Exploratory Endpoint	Report the range and average reduction in RMSE.	The average reduction in RMSE for the PET-only model for the default configuration is -0.040, with a range of -0.172 to 0.009. The average reduction in RMSE for the PET/CT model for the default configuration is -0.028, with a range of -0.150 to 0.070.
Image Quality (Structural Similarity Index Measure) Exploratory Endpoint	Report the range and average increase in SSIM.	The average SSIM for the PET-only model for the default configuration is 0.019, with a range of -0.018 to 0.106. The average SSIM for the PET/CT model for the default configuration is 0.009, with a range of -0.064 to 0.057.
Image Quality (SUVmax) Exploratory Endpoint	Report difference in SUVmax.	The following is the average difference in SUVmax for the PET-only model for the default configuration with each tracer: • 18F-FDG: 0.94% • 18F-DCFPyL: -0.66% • 68Ga-Dotatate: -1.53% • 18F-Choline: -1.03% • 68Ga-PSMA: 2.32% • 18F-DOPA: 2.25% The following is the average difference in SUVmax for the PET/CT model for the default configuration with each tracer: • 18F-FDG: -2.17% • 18F-DCFPyL: -6.74% • 68Ga-Dotatate: 1.00%

Reader Study:

This study utilized retrospectively acquired human data obtained as part of research studies or clinical exams from various institutions. The data set included *203 studies (203 SubtleHD-PET, 203 SOC) used to validate the PETonly model and 122 studies (122 SubtleHD-PET, 122 SOC) used to validate the PET/CT model*. The datasets were presented side-by-side with standard-of-care and SubtleHD-PET enhanced images.

Board-certified nuclear medicine physicians evaluated SubtleHD-PET-enhanced images for image quality/diagnostic confidence using a 5-point Likert scale, assessed artifacts using a 3-point Likert scale, and evaluated false positives and false negatives using lesion counts.

The following are the endpoints, acceptance criteria, results, and conclusions from the SubtleHD-PET Reader Study:

Table 4. Reader Study Summary

Endpoint	Acceptance Criteria	Result / Conclusion
Image Quality (IQ) / Diagnostic Confidence Primary Endpoint	The average scores across all readers of the SubtleHD-PET enhanced images are an average of 3 or better (enhanced images are the same or better than original).	PASS: SubtleHD-PET image quality / diagnostic confidence is the same or better than the standard-of-care images.
FP/FN Primary Endpoint	No false positives or false negatives are detected in the SubtleHD-PET images.	PASS: SubtleHD-PET does not introduce any false positives or false negatives.
Artifacts Evaluation Secondary Endpoint	SubtleHD-PET enhanced images have an average of 2 or better (SubtleHD-PET does not introduce artifacts that could impact diagnosis in any image)	PASS: SubtleHD-PET does not introduce artifacts that could impact diagnosis in any image.

Conclusion:

These results demonstrate that SubtleHD-PET is substantially equivalent to the predicate devices.