August 5, 2025

Claritas HealthTech Pte. Ltd.
Devika Dutt
COO
20A Tanjong Pagar Road
Singapore, 088443
Singapore

Re: K244016
Trade/Device Name: iPETcertum (v1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 2, 2025
Received: July 2, 2025

Dear Devika Dutt:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244016

Device Name

iPETcertum (v1.0)

Indications for Use *(Describe)*

iPETcertum is an image processing software intended for use by radiologists and nuclear medicine physicians for noise reduction, sharpening, resolution improvement, and optional segmentation based on uptake value in PET images (including PET/CT and PET/MRI) obtained with any kind of radionuclides, e.g. fluorodeoxyglucose (FDG). Enhanced images can be saved in DICOM, NIfTI or ECAT files and exist in conjunction with original images.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K244016

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

1. Submitter Information

Company:	Claritas HealthTech Pte. Ltd. 20A Tanjong Pagar Road Singapore, Singapore 088443
Contact:	Devika Dutt COO Claritas HealthTech Pte Ltd 20A Tanjong Pagar Road Singapore, Singapore 088443 Telephone: (91) 9011379804 d.d@claritasco.com
Date Summary Prepared:	December 27, 2024

2. Name of the Device

Trade Name:	iPETcertum (v1.0)
Model Number:	V1.0
Common Name:	Image Enhancement System
Device:	System, Image Processing, Radiological
Regulation Name:	Medical Imaging Management and Processing System
Review Panel:	Radiology
Regulation Number:	21 CFR 892.2050
Device Class:	Class II
Product Code:	LLZ

3. Equivalence Claimed to Predicate Device

The iPETcertum device is equivalent to the Claritas iPET (K213140) device, manufactured by Claritas HealthTech Pte Ltd.

4. Predicate Device Information

Trade Name:	Claritas iPET
Manufacturer:	Claritas HealthTech Pte Ltd
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical Imaging Management and Processing System
Device Class:	Class II
Product Code:	LLZ
510(k) Number:	K213140
510(k) Clearance Date:	December 22, 2021

5. Indications for Use

iPETcertum is an image processing software intended for use by radiologists and nuclear medicine physicians for noise reduction, sharpening, resolution improvement, and optional segmentation based on uptake value in PET images (including PET/CT and PET/MRI) obtained with any kind of radionuclides, e.g. fluorodeoxyglucose (FDG). Enhanced images can be saved in DICOM, NIfTI or ECAT files and exist in conjunction with original images.

6. Device Description

iPETcertum is a Software as a Medical Device (SaMD), that implements image enhancement and processing algorithms to increase image quality of Positron Emission Tomography (PET) images and enable visualization of regions of interest based on quantification of uptake of values. The iPETcertum enhancement and processing provide an improved and enhanced image with optional segmentation based on standard uptake value (SUV) and volume thresholds as per clinician defined parameters. The original image/data is not altered and is available for comparison with the processed image.

iPETcertum can be used to enhance PET images with optional simultaneous Magnetic Resonance Imaging (MRI) or Computerized Tomography (CT) scans of the same subject. iPETcertum takes as input DICOM [Digital Imaging and Communications in Medicine], NIfTI [Neuroimaging Informatics Technology Initiative], or ECAT 7.x files of PET, MRI, and CT volumes, interactively visualizes the content, and produces an enhanced output of the same PET volume, in DICOM, NIfTI, or ECAT 7.x formats. The objective is to enhance the input data that are obscured and not clearly visible, to become more visible, sharper, and clearer through the image enhancement process. If CT or MR guide is available, iPETcertum computes the fusion of functional (from PET) and anatomic (from MR or CT) information. During this process, no new feature is introduced that did not exist in the PET data, just the existing features are emphasized if they are also supported by the anatomy or suppressed, if they belong to the noise and are not supported by the anatomy. Noisy scans can be enhanced reducing noise and improving clarity with the use of iPETcertum.

The iPETcertum software can be used to visualize regions of interest based on standard uptake values (SUV) and volume as per clinician defined parameters to provide additional visual

information to the clinician. High uptake voxels can be identified and grouped together into connected regions, referred to as segmentation. The Standard Uptake Value (SUV) is computed and connected regions belonging to the specified range are segmented and quantified.

7. Substantial Equivalence Comparison of Technological Characteristics

The predicate device, Claritas iPET and the subject device, iPETcertum have similar technological characteristics. The subject device is an upgraded version of the predicate device. Both devices are based on the same core technology. Both devices implement an image processing algorithm based on the 3D non-local means filter optionally using a guide from a different 3D scan. The difference between the two devices is that the subject device, iPETcertum optionally transforms the data before and after filtering to make the noise characteristics more suitable for the non-local means filter. Additionally, the subject device has added functionality to locate, evaluate and visualize lesions in the original and enhanced scans. Verification and Validation testing and Performance testing for the subject device have been performed on static and dynamic PET, PET/MR and PET/CT scans, and the test results confirm that the subject device is as safe and effective as the predicate device, hence the differences in the technological characteristics do not raise new risks related to the safety and effectiveness.

The table below shows the similarities and differences between the technological characteristics of the two devices.

8. Technological Characteristics Comparison Table

Characteristics	**Predicate Device** Claritas iPET [K213140]	**Subject Device** **iPETcertum (v1.0)**
Device Class	Class II	Class II
Product Code	LLZ	LLZ
Manufacturer	Claritas HealthTech Pte Ltd	Same
Intended Use	An image processing software for image enhancement and processing of PET images including PET/CT and PET/MRI	Same
Indications for Use	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.	iPETcertum is an image processing software intended for use by radiologists and nuclear medicine physicians for noise reduction, sharpening, resolution improvement, and optional segmentation based on uptake value in PET images (including PET/CT and PET/MRI) obtained with any kind of radionuclides, e.g. fluorodeoxyglucose (FDG). Enhanced images can be saved in DICOM, NIfTI or ECAT files and exist in conjunction with original images.
Physical Characteristics	Software package that operates deployed on a local computer.	Same

Characteristics	**Predicate Device** Claritas iPET [K213140]	**Subject Device** **iPETcertum (v1.0)**
File Formats processed	DICOM	DICOM, NIfTI or ECAT
Original Scan	Original scan image/data is not altered and is always available as a reference for the clinician	Same
Operating System	Windows/Linux	Same
Modalities	Multi-modality; specifically processes the PET data of PET, PET/CT and PET/MR scanners	Same
Core Technology	Image processing mathematical algorithms	Same
Algorithm Description for Image Enhancement	The new value of a voxel is determined by analysing the voxel values in its 3D cubical neighbourhood that can extend in any direction in a user specified way. The filtering process determines the filter weights of the neighbourhood voxels according to the similarity of the PET data and optionally the similarity of the CT or MR data according to the Non-Local Means principles. The iPET image enhancement algorithm is a modification of the Non-Local Means algorithm where the filtering weights can be optionally and partially obtained from higher resolution and lower noise voxel arrays obtained with other modalities, i.e. CT or MR.	Same In addition, optional variance stabilization before filtering.
Segmentation Algorithm	Manual segmentation	Automated segmentation. Identification of lesion segments based on the activity range and the connectivity of high activity voxels.
Performance Metrics	PSNR (Peak Signal-to-Noise Ratio) SSIM (Structural-Similarity Index Measure) SNR (Signal-to-Noise-Ratio) RMSE (Root Mean Square Error)	Same In addition: DICE index
Workflow	It can input either individual or all slices of the PET, MR or CT scans as files, can interactively visualize the input and the output data, and save the enhanced volume in files in same format as input files.	Same Additional features: - PET scan, lesion information can be written into an excel file - Ability to produce video of 3D and 4D scans.

Summary of Technological Characteristics Comparison Table

As per the table able above the two devices are technologically similar and have similar indications of use. Verification, validation, and performance testing demonstrates the differences in the algorithm implemented by the subject and predicate, do not raise new questions of safety and effectiveness.

9. Performance Testing

iPETcertum has been developed under the Quality System Regulations of ISO 13485. The design has been verified and validated according to the software development plan which follows IEC 62304:2006 and ISO 14971:2019 requirements.

Safety and performance have been evaluated and verified in accordance with the software specification to ensure the performance meets the specified requirements and the requirement of the FDA guidance document, titled, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*". Testing included design traceability confirming all requirement tracing is complete from design inputs and verification/validation and that all risk controls are implemented. Design validation testing simulated intended use to confirm that the end-to-end functionality of the iPETcertum meets the design requirements.

Bench Performance Testing included the analysis of the improvement in the Signal to Noise Ratio (SNR), Peak Signal to Noise Ratio (PSNR), Structural Similarity (SSIM) and the Root Mean Square Error (RMSE) of PET images. The predicate device has presented performance testing data based on noise reduction.

The predicate device, Claritas iPET, has presented performance test results based on RMSE (root mean squared error), SNR (Signal-to-Noise-Ratio), Peak Signal-to-Noise Ratio (PSNR), and Structural-Similarity Index Measure (SSIM) improvement. The subject device, iPETcertum also presents performance test results based on these, and the test results confirm that the subject device is substantially equivalent to the predicate, and that there are no different concerns of safety or effectiveness raised.

In addition to these parameters, the performance testing for the subject device also covers other quality measures, including DICE score to measure the performance results of the lesion delineation and SUV measurement. The test results confirm that the subject device is substantially equivalent to the predicate, and that there are no different concerns of safety or effectiveness raised.

The validation and the performance testing evaluation of iPETcertum had three phases:

1. Using a mathematical phantom, the noise reduction was examined in a scenario where the ground truth is available, and the noise is varying in a controlled way. Filtering was executed with and without the added variance stabilization step. The acceptance criterion is that the RMSE is smaller or equal while SNR, SSIM, PSNR values are greater or equal for iPETcertum than for Claritas iPET. The test results confirmed that the SNR, PSNR and RMSE values are the same for Claritas iPET (predicate) and iPETcertum (subject) if the variance stabilization is disabled. With variance stabilization enabled, the SNR, PSNR have

been increased and the RMSE has been decreased by iPETcertum with respect to Claritas iPET in each of the test cases. The improvement is especially high when the original dataset is noisy due to the short time or low dosage scans. All test cases have passed successfully.

2. Long and high dose PET reconstructed results were accepted as the ground truth. The PET scanning time is decomposed to uniform frames, and the reconstruction process has been executed for subsets of the original frames demonstrating that the reconstruction quality can be maintained if the iPETcertum software is executed. The SNR, PSNR and SSIM have been increased and the RMSE has been decreased by iPETcertum with respect to the original, unprocessed scan. The acceptance criterion is that iPETcertum enhanced RMSE must be smaller or equal, and SNR must be greater or equal than those of iPET enhanced results. The test result confirms that iPETcertum quality measures are equal to or slightly better than those of the Claritas iPET. All test cases have passed successfully.

- For lesion segmentation the following was conducted:
    - The results of both subject and predicate devices are compared evaluating the volume, SUV average and SUV maximum values of the lesions. The pass criterion is that manual segmentation of Claritas iPET and automatic segmentation of iPETcertum produces similar SUV average, SUV maximum, and lesion volume values, and the difference from the ground truth is smaller for iPETcertum. All test cases have passed successfully.

    - A database of manually annotated scans is used as ground truth and the DICE index is computed for the iPETcertum segmentations. The acceptance criterion is that the iPETcertum contoured lesions and the manually segmented lesions must overlap with at least 50% DICE index. The study concluded that iPETcertum can identify lesions and provide estimates of their SUV, SUV maximum and volume values meeting and exceeding the acceptance criteria. All test cases have passed successfully.

10. Safety and Effectiveness

Based on the iPETcertum software performance test results and incorporated risk minimisation methods in design, Claritas HealthTech Pte. Ltd. concludes that this device is substantially equivalent to the predicate device.

11. Substantial Equivalence Conclusion

iPETcertum is an image enhancement software which has similar intended use and indications for use as the predicate device. The difference is that the subject, iPETcertum, has additional features including optional variance stabilization and automated lesion segmentation. The two devices have similar technological characteristics: both predicate device and subject device use the same image enhancement algorithms as their core technology. Performance test results and incorporated risk minimization methods demonstrate that iPETcertum is as safe and effective as the predicate device. These 510(k) submissions includes information on the iPETcertum technological characteristics, as well as performance data and verification and validation activities demonstrating that iPETcertum is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.