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

December 22, 2021

Re: K213140
Trade/Device Name: Claritas iPET
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 24, 2021
Received: September 27, 2021

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 (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
Thalia T. Mills, PhD
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213140

Device Name
Claritas iPET

Indications for Use *(Describe)*

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.

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

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

5.1 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: (65) 9795-1921 d.d@claritasco.com
Date Summary Prepared:	September 23, 2021

5.2 Name of the Device

Trade Name:	Claritas iPET
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

5.3 Equivalence Claimed to Predicate Device

The Claritas iPET device is equivalent to the SubtlePET (K182336) device, manufactured by Subtle Medical, Inc.

5.4 Predicate Device Information

Trade Name:	SubtlePET
Manufacturer:	Subtle Medical, Inc., 880 Santa Cruz Ave, Suite 200Menlo Park, CA 94025
Regulation Number:	21 CFR 892.2050
Regulation Name:	Picture archiving and communications system
Device Class:	Class II
Product Code:	LLZ
510(k) Number:	K182336
510(k) Clearance Date:	November 30, 2018

5.5 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.

5.6 Device Description

Claritas iPET v1.0 Image Enhancement System is a medical image enhancement software, i.e., a Software as a Medical Device (SaMD), that can be used to increase image quality by implementation of an image processing and image fusion algorithm.

Claritas iPET can be used to enhance Positron Emission Tomography (PET) images with optional simultaneous Magnetic Resonance Imaging (MRI) or Computerized Tomography (CT) scans of the same subject. Claritas iPET takes as input DICOM [Digital Imaging and Communications in Medicine] files of PET, MRI, and CT images, and produces an enhanced image of the same file. The objective is to enhance the DICOM files that are obscured and not clearly visible, to be more visible, sharper, and clearer through the Claritas iPET image enhancement process. Claritas iPET is intended to be used by radiologists and nuclear medicine physicians in hospitals, radiology centres and clinics, as well as by medical universities and research intuitions.

The image improvement includes noise reduction, sharpening of organ boundaries, and achieving super-resolution. With the help of Claritas iPET software, high quality PET scans can be produced. The Claritas iPET algorithm computes the fusion of functional (from PET) and anatomic (from MR or CT) information, and is based on Non-Local Means filtering. The goal of the software is to process and visualize the content of DICOM files storing 3D voxel arrays, i.e. a uniformly spaced sequence of slices of a PET scan. The processing algorithm may also input another 3D voxel array storing the density values obtained by a CT or MRI scan. The PET and CT/MR volumes should at least partially overlap to exploit the additional anatomic information. The CT or MR volume is expected to have a higher resolution than the

PET volume in order for effective improvement. The sharpness, style and the detail of the visualization can be controlled by the user and can be compared to the visualization of the raw image data. 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 are in the noise region and are not supported by the anatomy.

5.7 Substantial Equivalence Comparison of Technological Characteristics

The predicate device, SublePET and the subject device, Claritas iPET have similar technological characteristics. Both devices implement an image enhancement algorithm as the core of their image enhancement software. The predicate device implements an algorithm based on a trained convolutional neural network (CNN) and the subject device implements an algorithm based on 3D non-local means using a guide from a different 3D scan. The algorithms implemented in both devices enhance the image and reduce noise. Both devices predict the voxel value as a weighted sum of the values in the neighbourhood. The difference between the two devices is that the predicate device, SubtlePET finds the weights with a trained CNN, while the subject device, Claritas iPET finds the weights using the statistical analysis of the PET data and the data of additional modalities (MRI / CT). Verification and Validation testing and Performance testing for the subject device have been done 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.

5.8 Technological Characteristics Comparison Table

Characteristics	**Predicate Device** SubtlePET [K182336]	**Subject Device** Claritas iPET [K213140]
Device Class	Class II	Class II
Product Code	LLZ	LLZ
Intended Use	Image enhancement system which is an image processing software for image enhancement of PET images including PET/CT and PET/MRI	Same
Indications for Use	SubtlePET is an image processing software intended for use by radiologists and nuclear medicine physicians for transfer, storage, and noise reduction of fluorodeoxyglucose (FDG) and amyloid PET images (including PET/CT and PET/MRI).	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

Characteristics	**Predicate Device** SubtlePET [K182336]	**Subject Device** Claritas iPET [K213140]
		DICOM files and exist in conjunction with original images.
Physical Characteristics	Software package that operates on a virtual machine (VM)	Software package that operates on a virtual machine (VM) or deployed on a local computer.
Computer	Virtual machine host-compatible system	Virtual machine host-compatible system or local computer.
Image Processing Enhancement Location	Onsite on the facility VM and/or offsite on the cloud VM, depending on the site's configuration	Same in case of the PACS integrated version. The stand-alone version runs on the client computer.
DICOM standard Compliance	The software processes DICOM compliant image data	Same
Operating System	CentOS 7 Linux	Windows/Linux
Modalities	Multi-modality; specifically processes PET, PET/CT and PET/MR images	Same
User Interface	None – enhanced images are viewed on existing PACS workstations	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.
Protocols	Standard scanner protocols	Same
Core Technology	Image Enhancement Algorithm	Same
Image Enhancement Algorithm Description	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.	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.
Image acquisition	The acquisition remains the same, i.e. the image processing can be generated from multiple modalities and with predefined or specific acquisition protocol	The acquisition remains the same.

Characteristics	Predicate Device SubtlePET [K182336]	Subject Device Claritas iPET [K213140]
	settings.	
Workflow	The product acts as a DICOM node that receives DICOM 3.0 digital medical image data from the modality or another DICOM source, processes the data and then forwards the enhanced study to the selected destination. This destination can be any DICOM node, typically either the PACS system or a specific workstation.	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.

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.

5.9 Performance Testing

Claritas iPET 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 Claritas iPET meets the design requirements.

Claritas iPET is an image processing software which reduces the noise without blurring organ boundaries and compromising the true signal. The accuracy of the processing and the reduction of the noise can be quantified by the Root Mean Square Error (RMSE) and the Signal to Noise Ratio (SNR) calculated before and after processing the data with iPET. Both measures need the ground truth of the analysed data.

In order to obtain the ground truth, we consider two different options:

- In the first option, we enhanced real full body human PET scans. We executed a long scan and accepted the reconstructed results as 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 even for reduced scanning time and/or dosage if the Claritas iPET software is executed. The comparison is repeated for the case when the additional CT/MRI information is also utilized by the Claritas iPET software. We have concluded that the RMSE has been decrease by at least 10% and the SNR has been increased by at least 20%. However, for low dosage or

short time scans, the improvement can be significantly higher, the RMSE is decreased by 50% and the SNR can be increased by 4-5 times. All tests have passed.

- In the second option, we took the Zubal mathematical phantom, and considered it as the ground truth. The measured data are then generated by adding multiplicative, i.e. Poisson noise to the ground truth data. The noisy images are processed with the iPET software and the results are compared to the ground truth. The conclusions are similar to those of the measured scans. For high dosage and longer scans, we can expect 10-20% improvement in RMSE and SNR, which grows rapidly for low dosage or short scans. This test has passed.

5.10 Safety and Effectiveness

Based on the Claritas iPET 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.

5.11 Substantial Equivalence Conclusion

Claritas iPET is an image enhancement software which has similar intended use and indications for use as the predicate device. The difference is that the predicate device sets the filtering weights using a pre-trained neural net, while Claritas iPET applies multi-channel non-local means filtering. The two devices have similar technological characteristics: both predicate device and subject device use image enhancement algorithms as their core technology. Performance test results and incorporated risk minimization methods demonstrate that Claritas iPET is as safe and effective as the predicate device. This 510(k) submission includes information on the Claritas iPET technological characteristics, as well as performance data and verification and validation activities demonstrating that Claritas iPET is substantially equivalent to the predicate device, and does not raise different questions of safety and effectiveness.