ClariPI Inc
℅ Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

June 13, 2019.

Re: K183460
Trade/Device Name: ClariCT.AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 3, 2019
Received: May 7, 2019

Dear Mr. Alletto:

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, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183460

Device Name
ClariCT.AI

Indications for Use *(Describe)*
ClariCT.AI, is a software device intended for networking, communication, processing and enhancement of CT images in DICOM format regardless of the manufacturer of CT scanner or model.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of as required by section 807.92(c). K183460

I. SUBMITTER

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Contact person: Ms. Hyun-Sook Park, CEO

Date Prepared: May 3, 2019

II. DEVICE

Name of Device: ClariCT.AI

Common or Usual Name: Picture, archive and communications system

Classification Name: System, Image Processing, Radiological (21 CFR 892.2050)

Regulatory Class: II

Product Code: LLZ

III. PREDICATE DEVICE

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

The ClariCT.AI software device is substantially equivalent to K160852:

Device Classification Name	system, image processing, radiological
510(k) Number	K160852
Device Name	Zia
Applicant	Zetta Medical Technologies, LLC. 1313 Ensell Road Lake Zurich, IL 60047
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	03/28/2016
Decision Date	12/15/2016
510k Review Panel	Radiology

IV. DEVICE DESCRIPTION

ClariCT.AI software is intended for denoise processing and enhancement of CT DICOM images when higher image quality and/or lower dose acquisitions are desired. ClariCT.AI software can be used to reduce noises in CT images of the head, chest, heart, and abdomen, in particular in CT images with a lower radiation dose. ClariCT.AI may also improve the image quality of low-dose non-diagnostic Filtered Back Projection images as well as Iterative Reconstruction images.

The system enables the receipt of DICOM images from CT imaging devices (modalities), enables their denoise processing and enhancement, and transmission to a PACS workstation.

V. INDICATIONS FOR USE

ClariCT.AI, is a software device intended for networking, communication, processing and enhancement of CT images in DICOM format regardless of the manufacturer of CT scanner or model.

VI. SUBSTANTIAL EQUIVALENCE TABLE

The subject device (ClariCT.AI) is substantially equivalent to the predicate device (K160852, ZIA) which is also used for noise reduction and enhancement of CT images.

The following information compares the subject device to the predicate. The difference lies in noise reduction method where ClariCT.AI, the subject device uses pre-trained deep learning models whereas the predicate device uses regularization process at flat regions with data fidelity constraints at edges. It has no effect on the safety or efficacy of the subject device and does not raise any potential safety risks, and the subject device is identical in performance to the legally marketed device.

Item	Subject Device – ClariCT.AI	Predicate- ZIA (K160852)
Intended Use	ClariCT.AI is intended for networking, communication, processing and enhancement of CT images in DICOM format.	ZIA image enhancement system is an image processing software that can be used for reducing noise in CT images. Enhanced images will be uploaded back to host/PACS systems and exist in conjunction to the original images. ZIA, is not intended for mammography applications. The device processing is not effective for lesion, mass or abnormalities of sizes less than 2.0 mm.
Intended User	Radiologists and Specialists	Radiologists and Specialists
Modality Support	CT	CT
Noise Reduction Method	Noise reduction is performed with the use of pre-trained deep learning models.	Regularization process at flat regions with data fidelity constraints at edges.
Image Format and communications	DICOM	DICOM
Components and Hardware requirement	Window Operating System, PC Hardware, CUDA supported graphics card or equivalent.	Window Operating System, PC Hardware, CUDA supported graphics card or equivalent.

VII. PERFORMANCE DATA

Non-clinical performance testing has been performed on ClariCT.AI, (the subject device) and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971Medical devices – Application of risk management to medical devices
- NEMA-PS 3.1- PS 3.20 Digital Imaging and Communications in Medicine (DICOM)

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued May 11, 2005.
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices issued September 6, 2017.
- The subject device, was tested in accordance with the internal Verification and Validation processes of ClariPI Inc.. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications, and the risk management results.ClariCT.AI has been validated using:
    - The use of ACR CT Accreditation Phantom
    - A variety of clinical processed data:
        - Paired datasets of low and high doses for the same patients
        - IR & FBP datasets
        - Datasets for subgroup analysis of datasets with various genders, ages, body weights, races, and ethnicities
        - Datasets with varying scan conditions using scanners from different vendors for different organs

The test results in this 510(k), demonstrate that ClariCT.AI:

- complies with the aforementioned international and FDA-recognized consensus standards and
- FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, ClariCT.AI, is substantially equivalent to the currently marketed predicate device, in terms of safety and effectiveness.

Clinical Testing:

ClariCT.AI does not require clinical studies to demonstrate substantial equivalence to the predicate device.

VIII CONCLUSIONS

Verification and Validation activities required to establish the safety and effectiveness of ClarCT.AI, were performed. Testing involved system level tests, performance tests, and safety testing from risk analysis. Testing performed, demonstrated the subject device meets pre-defined functionality requirements.

The subject device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Test results with the phantom data and clinical processed dataset demonstrate that the subject device is as safe and effective and therefore substantially equivalent to the predicate device.