ClariPi Inc.
% Harry Park
President
ClariPi USA Inc.
1645 Park Creek Ct.
ROCHESTER HILLS MI 48309

July 27, 2021

Re: K212074
Trade/Device Name: ClariCT.AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 1, 2021
Received: July 2, 2021

Dear Harry Park:

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)*
K212074

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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).

I. SUBMITTER

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Seoul, Republic of Korea [03088]
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Email: claripi@claripi.com

Contact person: Ms. Hyun-Sook Park, CEO
Date Prepared: July 01, 2021

II. DEVICE

Name of Device: ClariCT.AI
Common or Usual Name: Picture, archive and communications system
Classification Name: Medical Image Management and Processing System (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, addressed in this premarket notification, is substantially equivalent to the following commercially available software:

Device Classification Name	Medical Image Management and Processing System
510(k) Number	K183460
Device Name	ClariCT.AI
Applicant	ClariPi Inc. 3F, 70-15, Ihwajang-gil, Jongno-gu Seoul, Korea, Republic of [03088]
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	12/13/2018
Decision Date	06/13/2019
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

510(k) Summary

improve the image quality of low-dose nondiagnostic Filtered Back Projection images as well as Iterative Reconstruction images.

The predicate device is a software application to denoise on CT images, integrated with the clinical environment through DICOM communication on-premise, and runs under the Microsoft Windows platform.

The subject device, ClariCT.AI, added a new module (named AI Marketplace Integration module) to the original cleared device (K183460) to enable installation on the AI Marketplace system. The module integrates the Denoising Processor of the original device into the AI Marketplace system. So ClariCT.AI can be hosted through a third-party AI marketplace that integrates centrally with PACS and seamlessly integrates into the existing IT and modality infrastructure.

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 following information compares the subject device to the predicate. The difference is that the subject device can be integrated into the AI Marketplace system that distributes Docker images in a virtual machine running in a Linux environment. 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 Device ClariCT.AI (K183460)
Intended 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.	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.
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.	Noise reduction is performed with the use of pre-trained deep learning models.
Image Format	DICOM	DICOM
Components And Hardware Requirement	Window Operating System, PC Hardware, CUDA supported graphics card or equivalent.	Window or Linux Operating System. PC Hardware supported graphics card or equivalent.

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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 14971 Medical 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.
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014.
- 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.

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 devices, in terms of safety and effectiveness.

Clinical Testing:

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

VIII CONCLUSIONS

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

The subject device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Test results with the substantial datasets demonstrate that the subject device is as safe and effective as the predicate devices. Therefore, the subject device is substantially equivalent to the predicate devices.