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

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.


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

I. SUBMITTER
ClariPI Inc.
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Seoul, Korea, Republic of [03088]
Tel: +82-2-741-3014
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Email: claripi@claripi.com

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:

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

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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device – ClariCT.AI</th>
<th>Predicate- ZIA (K160852)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>ClariCT.AI is intended for networking, communication, processing and enhancement of CT images in DICOM format.</td>
<td>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.</td>
</tr>
<tr>
<td>Intended User</td>
<td>Radiologists and Specialists</td>
<td>Radiologists and Specialists</td>
</tr>
<tr>
<td>Modality Support</td>
<td>CT</td>
<td>CT</td>
</tr>
<tr>
<td>Noise Reduction Method</td>
<td>Noise reduction is performed with the use of pre-trained deep learning models.</td>
<td>Regularization process at flat regions with data fidelity constraints at edges.</td>
</tr>
<tr>
<td>Image Format and communications</td>
<td>DICOM</td>
<td>DICOM</td>
</tr>
<tr>
<td>Components and Hardware requirement</td>
<td>Window Operating System, PC Hardware, CUDA supported graphics card or equivalent.</td>
<td>Window Operating System, PC Hardware, CUDA supported graphics card or equivalent.</td>
</tr>
</tbody>
</table>

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)
510(k) Summary

- 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 ClariCT.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.