April 6, 2022

ClariPi Inc.
% Harry Park
President
ClariPi Detroit Office
1645 Park Creek Ct. Rochester Hills
DETROIT MI 48309

Re: K203783
Trade/Device Name: ClariPulmo
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 31, 2022
Received: March 31, 2022

Dear Mr. 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,

Laurel Burk, Ph.D
Assistant Director
Diagnostic X-ray Systems Team
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)*
K203783

Device Name
ClariPulmo

Indications for Use *(Describe)*
ClariPulmo is a non-invasive image analysis software for use with CT images which is intended to support the quantification of lung CT images. The software is designed to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from the CT thoracic datasets. (The software is not intended for the diagnosis of pneumonia or COVID-19). The software provides automated segmentation of the lungs and quantification of low-attenuation and high-attenuation areas within the segmented lungs by using predefined Hounsfield unit thresholds. The software displays by color the segmented lungs and analysis results. ClariPulmo provides optional denoising and kernel normalization functions for improved quantification of lung CT images in cases when CT images were taken at low-dose conditions or with sharp reconstruction kernels.

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

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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Contact person: Mr. Harry Park, ClariPi USA
Date Prepared: April 6, 2022

II. DEVICE

Device Name: ClariPulmo

Common or Usual Name: Radiological Image Processing Software

Regulation Name: “Medical Image Management and Processing System”

Regulation Number: 21 CFR 892.2050

Regulatory Class: II

K-Number: K203783

Product Code: LLZ

III. PREDICATE DEVICE

The following table shows the predicate devices of the proposed ClariPulmo:

Device Classification Name	System, Image processing, Radiological (Predicate device)
510(k) Number	K103480
Device Name	THORACIC VCAR
Applicant	GE MEDICAL SYSTEMS, LLC 3000 N GRANDVIEW Waukesha, WI 53188, USA
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	11/26/2010
Decision Date	03/07/2011
510k Review Panel	Radiology

The proposed ClariPulmo and its predicate devices, THORACIC VCAR (K103480) is substantially equivalent regarding its intended use, clinical indications, and principle of operation.

Further to the predicate device, ClariPi has identified the following currently marketed devices as reference devices of proposed ClariPulmo:

Device Classification Name	System, X-Ray, Tomography, Computed (Reference Device)	System, X-Ray, Tomography, Computed (Reference Device)	System, Image processing, Radiological (Reference Device)
510(k) Number	K141069	K200990	K183460
Device Name	Imbio CT Lung Density Analysis Software	VIDA|vision (formerly VIDA Pulmonary Workstation 2 (PW2))	ClariCT.AI
Applicant	IMBIO LLC 227 COLFAX AVE NSUITE 144 Minneapolis, MN 5 5405 USA	VIDA Diagnostics, Inc. 500 Crosspark Rd. W250 BioVentures Center Coralville, IA 52241 USA	ClariPi Inc. 3F, 70-15, Ihwajang-gil, Jongno-gu, Seoul, Republic of Korea [03088]
Regulation Number	892.1750	892.1750	892.2050
Classification Product Code	JAK	JAK	LLZ
Date Received	04/24/2014	04/15/2020	12/13/2018
Decision Date	09/17/2014	08/07/2020	06/13/2019
Decision	Substantially Equivalent (SE)	Substantially Equivalent (SE)	Substantially Equivalent (SE)
Regulation Medical Specialty	Radiology	Radiology	Radiology

The Imbio CT Lung Density Analysis Software (K141069), VIDA|vision (formerly VIDA Pulmonary Workstation 2 (PW2)) (K200990) and ClariCT.AI (K183460) are reference devices for additional technologies and support the addition application functionalities and enhanced capabilities.

IV. DEVICE DESCRIPTION

ClariPulmo is a standalone software application analyzing lung CT images that can be used to support the physician in the quantification of lung CT image when examining pulmonary tissues.

ClariPulmo provides two main and optional functions:

- LAA Analysis provides quantitative measurement of pulmonary tissue image with low attenuation areas (LAA). LAA are measured by counting those voxels with low attenuation values under the user-predefined thresholds within the segmented lungs. This feature supports the physician in quantifying lung tissue image with low attenuation area.

- HAA Analysis provides quantitative measurement of pulmonary tissue image with high attenuation areas (HAA). HAA are measured by counting those voxels with high attenuation

values using the user-predefined thresholds within the segmented lungs. This feature supports the physician in quantifying lung tissue image with high attenuation area.

- Lungs are automatically segmented using a pre-trained deep learning model.
- The optional Kernel Normalization function provides an image-to-image translation from a sharp kernel image to a smooth kernel image for improved quantification of lung CT images. The Kernel Normalization algorithm was constructed based on the U-Net architecture.
- The optional Denoising function provides an image-to-image translation from a noisy low-dose image to a noise-reduced enhanced quality image of LDCT for improved quantification of lung LDCT images. The Denoising algorithm was constructed based on the U-Net architecture.

The ClariPulmo software provides summary reports for measurement results that contains color overlay images for the lungs tissues as well as table and charts displaying analysis results.

v. INDICATIONS FOR USE

ClariPulmo is a non-invasive image analysis software for use with CT images which is intended to support the quantification of lung CT images. The software is designed to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from the CT thoracic datasets. (The software is not intended for the diagnosis of pneumonia or COVID-19). The software provides automated segmentation of the lungs and quantification of low-attenuation and high-attenuation areas within the segmented lungs by using predefined Hounsfield unit thresholds. The software displays by color the segmented lungs and analysis results. ClariPulmo provides optional denoising and kernel normalization functions for improved quantification of lung CT images in cases when CT images were taken at low-dose conditions or with sharp reconstruction kernels.

Subject Device (K203783)	Predicate Device (103480)
ClariPulmo is a non-invasive image analysis software for use with CT images which is intended to support the quantification of lung CT images. The software is designed to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from the CT thoracic datasets. (The software is not intended for the diagnosis of pneumonia or COVID-19). The software provides automated segmentation of the lungs and quantification of low-attenuation and high-attenuation areas within the segmented lungs by using predefined Hounsfield unit thresholds. The software displays by color the segmented lungs and analysis results. ClariPulmo provides optional denoising and kernel normalization functions for improved quantification of lung CT images in cases when CT images were taken at low-dose conditions or with sharp reconstruction kernels.	Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease diagnosis and management. The software will provide automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree. The software will provide quantification of Hounsfield units and display by color the thresholds within a segmented region.

VI. INTENDED POPULATION

The device is intended for adult patients receiving lung CT.

VII. SUBSTANTIAL EQUIVALENCE TABLE

Feature	ClariPulmo (Subject Device)	Thoracic VCAR K103480 (Predicate Device)	Imbio CT Lung Density Analysis Software K141069 (Reference Device)	VIDA|vision (formerly VIDA Pulmonary Workstation 2 (PW2)) K200990 (Reference Device)	ClariCT.AI K183460 (Reference Device)
Algorithm	Deep learning	unknown	Image post-processing algorithm	Self-contained image analysis	Deep learning
Modality	CT	CT	CT	CT	CT
Type of scan	Thoracic CT	Thoracic CT	Thoracic CT	Thoracic CT	Head, heart, chest and abdomen CT
DICOM standard	Yes	Yes	Yes	Yes	Yes
Automatic segmentation of both the left and right lungs and airways	Yes	Yes	Yes	Yes	Not relevant
Lung volume analysis support: Both, Left, and Right Lungs	Yes	Yes	Yes	Yes	Not relevant
Low attenuation analysis	Yes Lung density result quantification with HU density range, volume measurement, lung density index and Perc15 measurement	Yes Lung density result quantification with HU density range, volume measurement	Yes Lung density result quantification with HU density range, volume measurement, lung density index and PercX (where "X" corresponds to the desired percentile) calculated in the Inspiration Assessment only.	Yes Lung density result quantification with HU density range, volume measurement, lung density index and Perc15 measurement	Not relevant

High attenuation analysis	Yes Lung density result quantification with HU density range and volume measurement based on selected HU ranges set by user	Yes Lung density result quantification with HU density range and volume measurement based on selected HU ranges set by user	Not supported	unknown	Not relevant
Adjustable density thresholds for refining and optimizing HU range	Yes	Yes	Not supported	Yes	Not relevant
Viewer displays lung density in color according to Hounsfield Unit (HU) range.	Yes	Yes	Yes	Yes	Not relevant
Viewer displays density graph/histogram of the classified lung voxels' relative frequencies	Yes	Unknown	Yes	Yes	Not relevant
Report includes overlay of density quantification results and density graph histogram	Yes	Unknown	Yes	Yes	Not relevant
Low-dose CT support	Yes	Not supported	Yes	Yes	Yes

VIII. PERFORMANCE TESTING

Non-clinical performance testing has been performed on ClariPulmo (the subject device) to support the safety and effectiveness of the features including the HAA and LAA analysis, AI-based lung segmentation, AI-based kernel normalization and denoising.

The HAA analysis showed excellent agreement (PCC: 0.980 – 0.983) with expert-established segmentations of user-defined high attenuation areas. The test dataset used for manual vs threshold-based segmentations included patients with pneumonia and COVID-19.

The LAA analysis showed excellent agreement (PCC: 0.99) with expert-established segmentations of user-defined low attenuation areas. The test dataset used for manual vs threshold-based segmentations included both health and diseased patients.

The AI-based lung segmentation demonstrated excellent agreements with that by expert radiologist's imageJ based segmentation for one internal and two external datasets showing PCC of 0.977~0.992 and DICE coefficients of 0.98~0.99 with statistical significance across normal/LAA/HAA patients, CT scanner, reconstructed kernel and low-dose subgroups . The submitted performance testing data 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.
- 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 ClariPulmo:

- 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, ClariPulmo, is substantially equivalent to the currently marketed predicate device, in terms of safety and effectiveness.

Clinical Testing:
ClariPulmo does not require clinical studies to demonstrate substantial equivalence to the predicate device.

IX. CONCLUSIONS

Verification and Validation activities required to establish the safety and effectiveness of ClariPulmo 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 does not raise any new potential risks and is equivalent in performance to existing legally marketed devices. Nonclinical tests demonstrate that the subject device is as safe and effective and therefore substantially equivalent to the predicate device.