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

September 10, 2021

Re: K203785
Trade/Device Name: ClariSIGMAM
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: August 9, 2021
Received: August 9, 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,

Jessica Lamb

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)*
K203785

Device Name
ClariSIGMAM

Indications for Use *(Describe)*
ClariSIGMAM is a software application intended for use with compatible full field digital mammography systems. ClariSIGMAM calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. ClariSIGMAM uses this numerical value to provide breast density group information (BI-RADS A+B as fatty and BI-RADS C+D as dense) to aid interpreting physicians in the assessment of breast tissue composition. ClariSIGMAM produces adjunctive information. It is not a diagnostic aid.

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

K203785

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

I. SUBMITTER

ClariPi Inc.
3F, 70-15, Ihwajang-gil, Jongno-gu
Seoul, Korea, Republic of [03088]
Tel: +82-2-741-3014
Fax: +82-2-743-3014
Email: claripi@claripi.com

Contact person: Ms. Hyun-Sook Park, CEO
Date Prepared: September 09, 2021

II. DEVICE

Name of Device: ClariSIGMAM
Common or Usual Name: Automated Radiological Image Processing Software
Classification Name: Medical image management and processing (21 CFR 892.2050)
Regulatory Class: II
Product Code: QIH

III. PREDICATE DEVICE

This predicate has not been subject to a design-related recall.
The ClariSIGMAM software device, addressed in this premarket notification, is substantially equivalent to the following commercially available software:

Device Classification Name	System, Image processing, Radiological
510(k) Number	K170540
Device Name	DM-Density
Applicant	Densitas, Inc. 1344 Summer Street, Suite 311.2 Halifax, CA B3h 0A8
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	02/13/2017
Decision Date	02/23/2018
510k Review Panel	Radiology

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

Device Classification Name	System, Image processing, Radiological
510(k) Number	K132742
Device Name	iReveal (formerly M-Vu Breast Density)

Applicant	iCAD, Inc. (formerly VuCOMP, Inc.) 98 Spit Brook Road, Suite 100 Nashua, NH 03062 USA
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	09/03/2013
Decision Date	12/03/2013
510k Review Panel	Radiology

IV. DEVICE DESCRIPTION

ClariSIGMAM software is a standalone software application that automatically analyzes "for presentation" 2D digital mammograms to assess breast tissue composition.
The software assesses the breast density of women and generates a breast density group information for the patient (BI-RADS A+B as fatty and BI-RADS C+D as dense) in accordance with the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) density classification scale.
Output of breast density by ClariSIGMAM is designed to display on a mammography workstation or PACS as DIOCM mammography structured report or secondary capture. The reports are configured to provide the following data:

- Breast area (cm^2) for each breast
- Fibroglandular tissue area (cm^2) for each breast
- Percent breast density for each breast
- Breast density group information for the patient (BI-RADS A+B as fatty and BI-RADS C+D as dense)

V. INDICATIONS FOR USE

ClariSIGMAM is a software application intended for use with compatible full field digital mammography systems. ClariSIGMAM calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. ClariSIGMAM uses this numerical value to provide breast density group information (BI-RADS A+B as fatty and BI-RADS C+D as dense) to aid interpreting physicians in the assessment of breast tissue composition. ClariSIGMAM produces adjunctive information. It is not a diagnostic aid.

VI. SUBSTANTIAL EQUIVALENCE TABLE

The subject device (ClariSIGMAM) is substantially equivalent to the predicate devices (K170540, DM-Density) which also calculate breast density as a ratio of fibro-glandular tissue and total breast area estimates. Both devices are not to be used as diagnostic aids, but to provide adjunctive information only. Users in both cases must be qualified medical practitioners and exercise their professional judgment when formulating diagnostic decisions and selecting appropriate treatment paths that are supported by breast density data. Both devices utilize standard DICOM communications protocol to receive Digital mammograms, processes them and automatically transfers the DICOM summary report to the picture archiving and communication system (PACS).

The difference lies in image source modalities and breast density category. The subject device is compatible and validated to certain Hologic and GE digital mammography systems whereas the predicate device (K170540) is compatible with Hologic Selenia Dimensions and Hologic Lorad Selenia the reference device (K132742) is compatible with all digital radiography (DR) systems and computer radiography (CR) systems. The predicate device reports four BI-RADS categories as the output of the device whereas the subject device reports dense (BI-RADS C+D) versus fatty (BI-RADS A+B). 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.

The following information compares the predicate devices and the subject device.

Item	Subject Device – ClariSIGMAM	Predicate Device- DM-Density (K170540)	Reference Device - M-Vu Breast Density (K132742)
Intended Use / Indication for Use	ClariSIGMAM is a software application intended for use with compatible full field digital mammography systems. ClariSIGMAM calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates and provides breast density group information (BI-RADS A+B as fatty and BI-RADS C+D as dense) to aid radiologists in the assessment of breast tissue composition. ClariSIGMAM produces adjunctive information. It is not a diagnostic aid.	DM-Density is a software application intended for use with compatible full field digital mammography systems. DM-Density calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. DM-Density provides these numerical values for each breast as well as a density category to aid interpreting physicians in the assessment of breast tissue composition. DM-Density produces adjunctive information. It is not a diagnostic aid.	M-Vu Breast Density is a software application intended for use with digital mammography systems. M-Vu Breast Density calculates breast density as a ratio of fibroglandular tissue and total breast area estimates. M-Vu Breast Density provides these numerical values for each breast as well as a density category to aid radiologists in the assessment of breast tissue composition. M-Vu Breast Density produces adjunctive information, It is not an interpretive or diagnostic aid.
Intended User	Interpreting Physicians, Radiologists and Specialists	Interpreting Physicians	Interpreting Physicians
Image Source Modalities	GE Senograph 2000D GE Senograph DS GE Senographe Pristina Hologic Selenia Dimensions Hologic Lorad Selenia	Hologic Selenia Dimensions Hologic Lorad Selenia	All digital radiography (DR) systems and computed radiography (CR) systems
Image	DICOM digital	DICOM full field digital	DICOM digital

Item	Subject Device – ClariSIGMAM	Predicate Device- DM-Density (K170540)	Reference Device - M-Vu Breast Density (K132742)
Format	mammography imager – For Presentation; RCC, LCC, RMLO, LMLO	mammography imager – For Presentation; RCC, LCC, RMLO, LMLO	mammography imager – For Processing; RCC, LCC, RMLO, LMLO
Output Data	For each breast: • Area of fibroglandular tissue (cm²) • Area of breast (cm²) • Area-based breast density (%) For each patient: • Breast density group information for the patient (BI-RADS A+B as fatty and BI-RADS C+D as dense)	**BI-RADS 4th Ed.** For each breast: • Area of fibroglandular tissue (cm²) • Area of breast (cm²) • Area-based breast density (%) For each patient: DM-Density breast density grade and percent breast density **BI-RADS 5th Ed.** For each patient: DM-Density breast density grade	For each breast: • Area of fibroglandular tissue (cm²) • Area of breast (cm²) • Area-based breast density (%) For each patient: VuCOMP density grade/BIRADS breast density

VII. PERFORMANCE DATA

Non-clinical performance testing has been performed on ClariSIGMAM, (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.
- 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. Validation testing included:
  - ClariSIGMAM-generated breast density estimates on substantial data sets were compared with Gold Standard breast density estimates which were established by generating breast density measurements using an interactive thresholding software (Cumulus, Sunnybrook Health Sciences Centre, Toronto, ON, Canada) by expert radiologist.
  - Reproducibility for what is known to decrease breast density with age was evaluated by running ClariSIGMAM on a substantial data set.
  - Breast density estimates with ClariSIGMAM were made on a paired set of mammograms with a maximum imaging period of a one year apart in order to assess if ClariSIGMAM-generated breast density estimates were reproducible over time.
  - ClariSIGMAM was run over substantial data sets and the breast density estimates for left and right breasts were compared to confirm that the results are similar for each view.

- Comparison of breast density group information (BI-RADS A+B as fatty and BI-RADS C+D as dense) between experts' visual assessment and automated assessment with ClariSIGMAM was assessed on reference standard dataset for BI-RADS breast density category that was established by a consensus visual assessment of expert readers according to BI-RADS 5th Edition.

ClariSIGMAM results were compared to a consensus assessment from four expert readers' independent assessments of breast density category on a dataset that spanned all compatible FFDM systems. The results for the binary density task using are summarized below:

- Confusion matrix for ClariSIGMAM and the reference standard on binary breast density task (BI-RADS A+B as fatty vs. BI-RADS C+D as dense).

  n=837; Kappa 0.734 [0.688, 0.781]

		Readers' consensus		
		Fatty	**Dense**	Accuracy
ClariSIGMAM	**Fatty**	293	63	86.6%
	Dense	45	436	87.3%
	Total	338	499	

The test results in this 510(k), demonstrate that ClariSIGMAM:

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

Clinical Testing:

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

VIII CONCLUSIONS

Verification and Validation activities required to establish safety and effectiveness of ClariSIGMAM, 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.