DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 28, 2016

ClearView Diagnostics, Inc.
% Ms. Christine Podilchuk
CEO
371 Hoes Lane, Suite 205
PISCATAWAY NJ 08854

Re: K161959
Trade/Device Name: ClearView cCAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 23, 2016
Received: November 28, 2016

Dear Ms. Podilchuk:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161959

Device Name
ClearView cCAD

Indications for Use *(Describe)*
ClearView cCAD is a software application designed to assist skilled physicians in analyzing breast ultrasound images. ClearView cCAD automatically classifies shape and orientation characteristics of user-selected regions of interest (ROIs).

The software allows the user to annotate, tag, measure, and automatically record and/or store selected views. The software also automatically generates reports from user inputs annotated during the image analysis process as well as the automatically generated characteristics. The output of this system will be a DICOM compatible (e.g. grayscale softcopy presentation state (GSPS)) and/or PDF report that can be sent along with the original image to standard film or paper printers or sent electronically to an intranet webserver or other DICOM compatible device.

cCAD includes options to annotate and describe the image based on the ACR BI-RADS® Breast Imaging Atlas. In addition, the report form has been designed to support compliance with the ACR BI-RADS ® Ultrasound Lexicon Classification Form.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decision should not be made solely on the results of the cCAD analysis. The ultrasound images displayed on cCAD must not be used for primary diagnostic interpretation.

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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5. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter: ClearView Diagnostics Inc.
Address: 371 Hoes Lane Suite 205
Piscataway, NJ 08854
Phone: 732-529-5755
Fax: 732-529-5757
Contact: Christine Podilchuk
Title: CEO
Phone: 908-616-1945
Fax: 732-529-5757

Summary Date: October 21, 2016

2. Identification of Product:

Device Name: ClearView cCAD, Version 1.1.0
Device Common Name: Image Analysis Software
Device Classification: 21 CFR 892.2050, Class II, LLZ (90)
Classification Name: Image Processing System
Manufacturer: ClearView Diagnostics Inc.

3. Marketed Devices

The ClearView cCAD system provides an automated analysis of lesion characteristics in order to facilitate the proper assessment of lesion characteristics and compliance with the ACR BI-RADS® ultrasound lexicon classification form. In terms of safety and performance, this software medical device is substantially equivalent to the device listed below:

Model: B-CAD System, Version 1.0
Manufacturer: The Medipattern Corporation
510(k) Numbers: K050846

4. Device Description

ClearView cCAD is a software application designed to assist skilled physicians in analyzing breast ultrasound images. ClearView cCAD automatically classifies shape and orientation characteristics of user-selected regions of interest (ROIs). The device uses multivariate pattern recognition methods to perform characterization and classification of images.

For breast ultrasound, these pattern recognition and classification methods are used by a radiologist to analyze such features as shape, orientation, and putative BI-RADS® category which can then be used to describe the lesion in the ACR BI-RADS® breast ultrasound lexicon as well as assigning an ACR BI-RADS® categorization which is intended to support compliance with the ACR BI-RADS® ultrasound lexicon classification form. Similarly, this process can be used to assist in training, evaluation, and tracking of physician performance.

The cCAD software can be run on any Windows 7 or higher or Windows Embedded platform that has network, Microsoft IIS, and Microsoft SQL support and is cleared for use in medical imaging. The software does not require any specialized hardware, but the time to process ROIs will vary depending on the hardware specifications. ClearView cCAD is based on core BI-RADS models and lesion characteristic extraction algorithms that can use novel statistical, texture, shape, orientation descriptors, and physician input to help with proper ACR BI-RADS® assessment.

The ClearView cCAD processing software is a platform agnostic web service that queries and accepts DICOM compliant digital medical files from an ultrasound device, another DICOM source, or PACS server. To initiate analysis and processing, images are queried from a compatible location and loaded for display within the application. The user then selects an ROI to analyze by clicking and dragging a bounding box around the region requiring analysis. Once selected, the user then clicks the processing button which initiates the analysis and processing sequence. The results are displayed to the user on the monitor and can then be selected for automated reporting, storage, or modification. The output of this system will be a DICOM compatible overlay (e.g. grayscale softcopy presentation state (GSPS)) and/or PDF report that can be sent along with the original image to standard film or paper printers or sent electronically to an intranet webserver or other DICOM compatible devices distributed by various OEM vendors. All fields may be modified by the user at any time during the analysis and prior to archiving.

5. Indications for Use

ClearView cCAD is a software application designed to assist skilled physicians in analyzing breast ultrasound images. ClearView cCAD automatically classifies shape and orientation characteristics of user-selected regions of interest (ROIs).

The software allows the user to annotate, tag, measure, and automatically record and/or store selected views. The software also automatically generates reports from user inputs annotated during the image analysis process as well as the automatically generated characteristics. The output of this system will be a DICOM compatible (e.g. grayscale softcopy presentation state (GSPS)) and/or PDF report that can be sent along with the original image to standard film or paper printers or sent electronically to an intranet webserver or other DICOM compatible device.

cCAD includes options to annotate and describe the image based on the ACR BI-RADS® Breast Imaging Atlas. In addition, the report form has been designed to support compliance with the ACR BI-RADS ® Ultrasound Lexicon Classification Form.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decision should not be made solely on the results of the cCAD analysis. The ultrasound images displayed on cCAD must not be used for primary diagnostic interpretation.

6. Substantial Equivalence Chart

Product	**BCAD (**K050846**)**	**ClearView cCAD**
Characteristics	Software for automated analysis of breast ultrasound lesions.	Software for automated analysis of breast ultrasound lesions.
Intended Use	Computer aided analysis tool intended to assist skilled physicians in screening and diagnosis as well as compliance with ACR BI-RADS® ultrasound lexicon form.	Computer aided analysis tool intended to assist skilled physicians in screening and diagnosis as well as compliance with ACR BI-RADS® ultrasound lexicon form.
Physical Characteristics	Software Package Operates on off-the-shelf hardware	Software Package Operates on off-the-shelf hardware
Computer	PC compatible	PC compatible
Operating System	Windows XP, Windows 2000	Windows 7, and higher, Windows Embedded
Storage	Storage not supported	Storage not supported
Image Input	DICOM	DICOM

For further discussion, please see sections 7 and 8.

7. Indications for Use Comparison

The indications for use for ClearView cCAD are substantially equivalent to those from the predicate device BCAD with one minor exception. In the BCAD indications for use they indicate their software automatically segments lesions whereas the cCAD software does not automatically segment lesions. The segmentation is not needed in the ClearView cCAD automatic classification of shape and orientation characteristics. The performance of the cCAD system has been shown to be just as effective as a radiologist's performance without the additional segmentation step. This performance is comparable to the BCAD predicate device and as such, the omission of the automatic segmentation step does not impact the safety and effectiveness of the device when used as labeled.

In addition, patient management decisions are not being made solely based on the results from either the cCAD analysis or the BCAD output.

8. Features and Principles of Operation Comparison

ClearView cCAD is similar to predicate devices **BCAD (**K050846**)** as a software package that operates on standard off-the-shelf hardware and supports automated analysis of lesion shape and orientation in DICOM format. ClearView cCAD contains novel shape and orientation algorithms that likely differ from the algorithms used in the BCAD product. Since ClearView does not have access to the data BCAD was evaluated on, these algorithms have been tested for agreement against MQSA certified radiologists as described in section 18.

The cCAD software platform also does not perform segmentation of the lesions at any point in its pipeline for characteristics analysis and as such does not display segmentation results in contrast to the BCAD product. This difference also does not impact overall performance as assessed and described in section 18.

The cCAD client is web based, whereas the BCAD product was a standalone application. This raises the question of equivalence which is addressed by Software Requirements 120 and 122, specific mitigations were taken to ensure that all image analysis was performed on the original full resolution images and is agnostic to the display and/or hardware accessing the client. In addition, as per the IFU of both cCAD and its predicate devices, the cCAD software is not to be used as the primary diagnostic interpretation platform.

9. Non-Clinical Performance Data

Bench testing was performed to ascertain the degree of concordance with skilled physicians. Ground truth for shape and orientation supplied by three MQSA certified skilled physicians, each with over 20 years of experience and at least 3000 images read per year evaluated this dataset on the aforementioned parameters. The system was analyzed on 1204 cases which had majority decision on shape and 1227 lesions which had majority decision on orientation. The Clearview cCAD system was able to achieve overall accuracy that fell within the 95% confidence interval of the radiologist performance, rendering them statistically equivalent. Based on these metrics, the ability of ClearView's cCAD system to discern BI-RADS® based shape and orientation parameters was confirmed.

10. Conclusion

After analyzing bench testing data, it is the conclusion of ClearView Diagnostics that the ClearView cCAD System is as safe and effective as the predicate devices, has few technological differences, only a minor change to the indications for use, and only minor interface changes, thus rendering it substantially equivalent to the predicate device.