Claritas HealthTech Pte Ltd
℅ Ms. Devika Dutt
COO
20A Tanjong Pagar Road
Singapore 088443
SINGAPORE

October 20, 2021

Re: K212470
Trade/Device Name: iRAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 7, 2021
Received: September 13, 2021

Dear Ms. Dutt:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
**K212470**

Device Name

iRAD

Indications for Use *(Describe)*

iRAD Image Enhancement System is an image processing software than can be used for image enhancement of MRI, CT, and X-Ray images. Enhanced images will be sent to PACS server and exist in conjunction to the original images.

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 - K212470

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

## 5.1 Submitter Information

| | |
|---|---|
| **Company:** | Devika Dutt<br>COO<br>Claritas HealthTech Pte Ltd<br>20A Tanjong Pagar Road<br>Singapore, Singapore 088443 Singapore<br>Telephone: 6597951921<br>Fax: N/A<br>d.d@claritasco.com |
| **Contact:** | Devika Dutt<br>COO<br>Claritas HealthTech Pte Ltd<br>20A Tanjong Pagar Road<br>Singapore, Singapore 088443 Singapore<br>Telephone: 6597951921<br>Fax: N/A<br>d.d@claritasco.com |
| **Date Summary Prepared:** | August 3, 2021 |

## 5.2 Name of the Device

| | |
|---|---|
| **Trade Name:** | iRAD |
| **Common Name:** | Image Enhancement System |
| **Classification Name:** | Processing System, Radiological (21 CFR, 892.2050, LLZ) |
| **Review Panel:** | Radiology (RA) |
| **Regulation:** | 892.2050 |
| **Class:** | Class II |
| **Product Code:** | LLZ |

## 5.3 Equivalence Claimed to Predicate Device

The iRAD is equivalent to the ZOOM (K172768), manufactured by Zetta Medical Technologies, LL.

## 5.4 Predicate Device Information

Trade name: ZOOM

Manufacturer: Zetta Medical Technologies, LLC., 1313 Ensell Road, Lake Zurich, IL 60047

Regulation Number: 21 CFR 892.2050

Regulation Name: System, Image Processing, Radiological

Device Class: Class II

Product Code: LLZ

510(k) Number: K172768

510(k) Clearance Date: April 24, 2018

## 5.5 Indications for Use

iRAD Image Enhancement System is an image processing software than can be used for image enhancement of MRI, CT, and X-Ray images. Enhanced images will be sent to PACS server and exist in conjunction to the original images.

## 5.6 Device Description

iRAD v1.0 Image Enhancement System is a medical image enhancement software, i.e., a Software as a Medical Device (SaMD), that can be used to enhance images of MRI, CT and X-Ray. iRAD takes as input DICOM [Digital Imaging and Communications in Medicine] files of MRI, CT, and X-Ray images, and produces an enhanced output of the same file, in DICOM format that can be sent to a PACS server. The objective is to enhance the DICOM files that are obscured and not clearly visible, to be more visible, sharper, and clearer through the iRAD image enhancement process. The iRAD image enhancement is done by the implementation of an image enhancement algorithm.

iRAD is intended to be used by medical doctors, radiologists and clinicians in hospitals, radiology centers and clinics, as well as by medical universities and research intuitions. The system allows selection of input DICOM images from PACS servers. DICOM images are sent to the iRAD image enhancement server, where they are processed and sent back to the PACS server after enhancement. The enhanced and original images exist in conjunction and can be compared. The system provides the user with a set of adjustable parameters through which to control the degree of contrast and strength enhancement and noise suppression.

iRAD implements a modified contrast limited adaptive histogram equalization algorithm to improve the visibility of the image and it uses the iRAD guided filter to reduce noise. The original image is deconstructed into overlapping rectangular components. The equalization and matching algorithm is executed in overlapping rectangular regions, resulting in several level-of-detail layers. The enhanced and denoised image is reconstructed using the level-of-detail layers based on user-controlled parameters of noise suppression and detail enhancement.

## 5.7 Substantial Equivalence Comparison of Technological Characteristics

The subject device iRAD is substantially equivalent to the predicate device ZOOM. Both predicate and subject device are image enhancement systems that process images for enhancement. Both devices have similar

technological characteristics as both implement image enhancement algorithms as their core technology. The difference is that the predicate device, ZOOM applies its image enhancement system only to MRI images, whereas the subject device, iRAD applies its image enhancement system to MRI images and to CT and X-Rays images. The method and process of enhancement that iRAD uses for MRI images is the same as the method and process of enhancement that iRAD uses for CT and X-Ray images. Verification, validation and testing demonstrate that the difference in number of modalities do not raise new questions of safety or effectiveness for the subject device. The table below shows the similarities and differences between the technological characteristics of the two devices.

## 5.8 Technological Characteristics Comparison Table

| **Characteristics** | **Predicate Device**<br><br>**ZOOM [K172768]** | **Subject Device**<br><br>**iRAD** |
|---|---|---|
| Device Class | Class II | Same |
| Product Code | LLZ | Same |
| Intended Use | Image enhancement system which is an image processing software for image enhancement. | Same |
| Indications for Use | ZOOM Image Enhancement System is an image processing software that can be used for image enhancement in MRI images.<br><br>Enhanced images will be sent to PACS server and exist in conjunction to the original images. | iRAD Image Enhancement System is an image processing software that can be used for image enhancement in MRI, CT, and X-Ray images.<br><br>Enhanced images will be sent to PACS server and exist in conjunction to the original images. |
| Modalities | MRI | MRI, CT, X-Ray |
| Physical Characteristics | Software that operates on off-the-shelf hardware | Same |
| Computer | PC or PC Compatible | Same |
| DICOM standard Compliance | The software processes DICOM compliant image data | Same |
| Operating System | Windows | Windows / Linux |
| Image Processing Hardware | Intel i3 processor, 4GB RAM, 500GB Hard drive | Intel i7 processor, Nvidia GPU |
| Image Input | DICOM | Same |

| Characteristics | Predicate Device<br><br>ZOOM [K172768] | Subject Device<br><br>iRAD |
|---|---|---|
| Image Output | DICOM | Same |
| User Interface | The software works on radiology workstation. | The software works on radiology workstation, both offline and online. |
| Core Technology | Image Enhancement Algorithm | Same |
| Software Core | ZOOM Image Enhancement Algorithm<br><br>(Zetta's own trademark) | iRAD Image Enhancement Algorithm<br><br>(Claritas HealthTech's own trademark) |
| Comparison with original Image | The enhanced image can be compared to the original DICOM image as both exist in conjunction. | Same |
| Workflow | The software, which is installed on a remote computer, receives DICOM images, processes the received images and sends the enhanced images back to PACS server. | Same |

**Summary of Technological Characteristics Comparison Table**

As per the table able above the two devices are technologically similar. Verification, validation, and performance testing demonstrates the differences in modalities do not raise new questions of safety and effectiveness.

## 5.9 Performance Testing

iRAD has been designed, verified and validated according to the software development plan which is in compliance with IEC 62304:2006 requirements. Safety and performance has been evaluated and verified in accordance with software specification to ensure performance meets specified requirements and the requirement of the FDA guidance document, titled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

iRAD is an image processing software which has the objective of emphasizing small and dim features that otherwise could have been missed. To make dim features visible, the contrast is improved, which can be quantified by calculating the RMS contrast ratio. The information content visible in the enhanced image is increased, which can be quantified with the entropy, and the noise is reduced which is measured with the signal to noise ratio improvement.

The verification, validation and the performance evaluation of iRAD had three phases:

1. Using the mathematical Derenzo Phantom, the contrast ratio and entropy improvement were examined, in a scenario where the ground truth is available, and the noise is varying in a controlled way. The iRAD software

was also tested in a situation where the noise is greater than the just visible difference in the true signal. The contrast ratio and the entropy have been increased by iRAD in each of the test cases. All test cases have passed successfully.

2. A collection of 82 lower resolution and 21 high resolution X-Ray, 100 CT, 100 MRI, and 38 camera scans, haven been processed by iRAD to test the improvement in the contrast ratios and the entropy values as compared to the original images. As per the processed test results, the measured contrast ratio and the entropy values have been increased by iRAD in each of the test cases. This test passed.

3. The signal-to-noise ratio (SNR) improvement of iRAD has been analyzed and tested in the following methods:

a. Using two mathematical phantoms. As per test results the SNR is increased significantly by iRAD in all test cases. This test passed.

b. SNR improvement was also tested in MRI, CT and X-Ray scans. Based on test results it was concluded that the iRAD algorithm improves the SNR in all images tested by at least 50% without any degradation. This test passed.

## 5.10 Safety and Effectiveness

Based on the iRAD software performance test results and incorporated risk minimisation methods in design, Claritas HealthTech Pte. Ltd. concludes that this device is substantially equivalent to the predicate device.

## 5.11 Conclusion

iRAD is an image enhancement software which has similar intended use and indications for use as the predicate device. The difference is that the predicate device is a Single Modality image enhancement system where as iRAD is a Multi Modality image enhancement system. The two devices have similar technological characteristics: both predicate device and subject device use image enhancement algorithms as their core technology; both algorithms use image based guided filtering and reconstruction, and both methods have optimized parameters to ensure robustness of the algorithm. Performance test results and incorporated risk minimization methods demonstrate that iRAD is as safe and effective as the predicate device. This 510(k) submission includes information on the iRAD technological characteristics, as well as performance data and verification and validation activities demonstrating that iRAD is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.