RamSoft Inc.
℅ Deeksha Shukla
Compliance & Legal Officer
150 Wheeler Avenue
Toronto, Ontario M4L 3V4
CANADA

November 17, 2022

Re: K222476
Trade/Device Name: OmegaAI Image Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 7, 2022
Received: October 7, 2022

Dear Deeksha Shukla:

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, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: Office of 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K222476

Device Name: OmegaAI Image Viewer

Indications for Use *(Describe)*

OmegaAI Image Viewer is software for diagnostic and clinical review intended for use in General Radiology (images from modalities including CR, CT, DX, MR, MG, NM, US, PET, RG, SC, VL, XA, Film Digitizer), Interventional Radiology, cardiology, oncology, obstetrics and gynecology, gastroenterology, ENT, orthopedics, internal medicine, emergency medicine, dermatology, dentistry, cardiology, rheumatology, Pathology (i.e., to review captured images/videos from a sample) and other healthcare imaging applications.

OmegaAI Image Viewer is intended to be used with off the shelf computing devices. Display monitors used for reading medical images for diagnostic purposes must comply with applicable clinical requirements, regulatory approvals and with quality control requirements for their use and maintenance. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the OmegaAI Image Viewer is intended for diagnostic purposes (on desktop platforms) and as a non-diagnostic review tool (on mobile platforms) to be used by trained healthcare professionals. Display calibration and lighting conditions should be verified by viewing a test pattern prior to use for diagnostic purposes.

OmegaAI Image Viewer supports major desktop and mobile browsers such as Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows. OmegaAI Image Viewer displays both lossless and lossy compressed images. **Each healthcare professional must ensure that they have the necessary environment to ensure the appropriate image quality for their clinical purpose and determine the level of lossy image compression acceptable for their purpose. Lossy image compression should not be used for primary reading in mammography.**

OmegaAI Image Viewer can be utilized for image manipulation by radiology technologists or other healthcare professionals. OmegaAI Image Viewer can be used to verify images that are captured in a medical imaging system have a diagnostic quality, to correct viewing characteristics of the image such as orientation, rotation, contrast, as well as to add annotations to mark significant finding or provide guidance for radiologists.

OmegaAI Image Viewer can store annotations and measurements as DICOM presentation states without changing the original image data. OmegaAI Image Viewer can display annotations and measurements as an overlay on images from DICOM objects, and from Computer-Aided Diagnosis (CAD) and AI software. The viewer can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). OmegaAI Image Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and reports side by side with the images. This can be used side by side with a reporting tool to create diagnostic reports.

**Note: To protect confidential information and ensure data security, the OmegaAI Image Viewer has User Access Control (UAC) which prevents unauthorized access and modification of data.**

**OmegaAI Image Viewer runs in a web browser sand-box, thus it relies on the browser's handling of interruptions, low-memory conditions etc. The browser will give an error to the user when it is not able to perform due to an interruption.**

**Caution: Federal law restricts this device to sell by or on the order of a physician.**

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.**

and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and* a *person is not required to respond to,* a *collection of information unless it displays* a *currently valid 0MB number."*

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# 510(k) Summary

K222476

## Statement

The following information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "… 510(k) Summaries and 510(k) Statements…" (21 CFR 807.92) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

## Submitter General Company Information

Company: RamSoft, Inc.
Contact: Deeksha Shukla
Address: 150 Wheeler Avenue, Toronto ON M4L 3V4, Canada
Phone: +1 647-797-2745
Email: dshukla@ramsoft.com

## Device:

Trade Name: OmegaAI Image Viewer
Classification Name: Medical Image Management and Processing System (MIMPS)(21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ- Image Processing System
510(k) Number: K222476

## Predicate Devices

510(k) Number: K203249
Device Name: Nucleus.io
Company: Nucleus Health, LLC

510(k) Number: K141881
Device Name: RapidResults
Company: RamSoft Inc.

Date Prepared: August 11, 2022.

## General Device Description

OmegaAI Image Viewer is designed to view and manipulate medical images or videos created from diagnostic imaging systems such as X-ray, Computed tomography, Nuclear medicine, MRI, Ultrasound, laboratory systems, and images from other sources such as handheld devices and cameras, endoscopy or other sources of images and videos. It can perform various image manipulation activities and store the modifications as presentation state along with the original study for future reference. OmegaAI Image Viewer allows users to perform image manipulations using the Adjustment Tools, including window level, rotate, flip, pan, stack scroll, and magnify. Notably, users have access to Markup Tools such as annotate, angle, cobb angle, probe, Mark ROI, and measurement. OmegaAI Image Viewer is also capable of organizing all the captured images for a patient and

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presenting them in a zero-footprint, web user interface, allowing the users to view images in their preferred layout and enabling them to compare current images with prior images of the respective patient.

Available on popular mobile and desktop platforms with keyboard, mouse, and touch inputs, the OmegaAI Image Viewer provides access to medical images in a convenient way for health care professionals to use as a diagnostic viewer and for review purposes.

OmegaAI Image Viewer supports major desktop and mobile browsers such as Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows and Mac devices. The software can only be used for diagnostic purposes on desktop platforms, whereas on mobile platforms it can be utilized as a non-diagnostic review tool by trained health professionals.

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## Indication for Use

OmegaAI Image Viewer is software for diagnostic and clinical review intended for use in General Radiology (images from modalities including CR, CT, DX, MR, MG, NM, US, PET, RG, SC, VL, XA, Film Digitizer), Interventional Radiology, cardiology, oncology, obstetrics and gynecology, gastroenterology, ENT, orthopedics, internal medicine, emergency medicine, dermatology, dentistry, cardiology, rheumatology, Pathology (i.e., to review captured images/videos from a sample) and other healthcare imaging applications.

OmegaAI Image Viewer is intended to be used with off the shelf computing devices. Display monitors used for reading medical images for diagnostic purposes must comply with applicable clinical requirements, regulatory approvals and with quality control requirements for their use and maintenance. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the OmegaAI Image Viewer is intended for diagnostic purposes (on desktop platforms) and as a non-diagnostic review tool (on mobile platforms) to be used by trained healthcare professionals. Display calibration and lighting conditions should be verified by viewing a test pattern prior to use for diagnostic purposes.

OmegaAI Image Viewer supports major desktop and mobile browsers such as Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows. OmegaAI Image Viewer displays both lossless and lossy compressed images. **Each healthcare professional must ensure that they have the necessary environment to ensure the appropriate image quality for their clinical purpose and determine the level of lossy image compression acceptable for their purpose. Lossy image compression should not be used for primary reading in mammography.**

OmegaAI Image Viewer can be utilized for image manipulation by radiology technologists or other healthcare professionals. OmegaAI Image Viewer can be used to verify images that are captured in a medical imaging system have a diagnostic quality, to correct viewing characteristics of the image such as orientation, rotation, contrast, as well as to add annotations to mark significant finding or provide guidance for radiologists.

OmegaAI Image Viewer can store annotations and measurements as DICOM presentation states without changing the original image data. OmegaAI Image Viewer can display annotations and measurements as an overlay on images from DICOM objects, and from Computer-Aided Diagnosis (CAD) and AI software. The viewer can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). OmegaAI Image Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and reports side by side with the images. This can be used side by side with a reporting tool to create diagnostic reports.

**Note: To protect confidential information and ensure data security, the OmegaAI Image Viewer has User Access Control (UAC) which prevents unauthorized access and modification of data.**

**OmegaAI Image Viewer runs in a web browser sand-box, thus it relies on the browser's handling of interruptions, low-memory conditions etc. The browser will give an error to the user when it is not able to perform due to an interruption.**

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## Comparison with the Predicate Device

| Characteristics | Subject Device | Predicate Device | Predicate Device |
|---|---|---|---|
| Device Name | OmegaAI Image Viewer | RapidResults | Nucleus.io |
| Manufacturer | RamSoft Inc. | RamSoft Inc. | Nucleus Health, LLC |
| 510(k) Number | K222476 | K141881 | K203249 |
| Regulation Number, Class | 21 CFR 892.2050, Class II | 21 CFR 892.2050, Class II | 21 CFR 892.2050, Class II |
| Product Code | LLZ | LLZ | LLZ |
| Indication for Use | OmegaAI Image Viewer is software for diagnostic and clinical review intended for use in General Radiology (images from modalities including CR, CT, DX, MR, MG, NM, US, PET, RG, SC, VL, XA, Film Digitizer), Interventional Radiology, cardiology, oncology, obstetrics and gynecology, gastroenterology, ENT, orthopedics, internal medicine, emergency medicine, dermatology, dentistry, cardiology, rheumatology, Pathology (i.e., to review captured images/videos from a sample) and other healthcare imaging applications.<br><br>OmegaAI Image Viewer is intended to be used with off the shelf computing devices. Display monitors used for reading medical images for diagnostic purposes must comply with applicable clinical requirements, regulatory approvals and with quality control requirements for their use and maintenance. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the OmegaAI Image Viewer is intended for diagnostic purposes (on desktop platforms) and as a non-diagnostic review tool (on mobile platforms) to be used by trained healthcare professionals. Display calibration and lighting conditions should be verified by viewing a test pattern prior to use | This software displays medical images and associated documents. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the software is intended for use as a primary diagnostic and review tool for use by trained healthcare professionals.<br><br>Each healthcare professional must determine if the level of loss is acceptable for their purpose. This software is not suitable for primary diagnosis of mammograms.<br><br>**Caution: Federal law restricts this device to sell by or on the order of a physician.** | Nucleus.io is a software-based image management solution and PACS intended to be used by radiologists and other clinicians. Nucleus.io provides image receipt, diagnostic viewing, storage, distribution, enhancement, sharing, manipulation (mark up and adjustment tools), and networking of medical 2D/3D images at distributed locations. All modules of Nucleus.io are web-based and thus can operate completely remote.<br><br>Nucleus.io displays both lossless and lossy compressed images. For lossy images, the medical processional user must determine if the level of loss is acceptable for their purposes.<br><br>Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. |

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| | for diagnostic purposes.<br><br>OmegaAI Image Viewer supports major desktop and mobile browsers such as Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows. OmegaAI Image Viewer displays both lossless and lossy compressed images. **Each healthcare professional must ensure that they have the necessary environment to ensure the appropriate image quality for their clinical purpose and determine the level of lossy image compression acceptable for their purpose. Lossy image compression should not be used for primary reading in mammography.**<br><br>OmegaAI Image Viewer can be utilized for image manipulation by radiology technologists or other healthcare professionals. OmegaAI Image Viewer can be used to verify images that are captured in a medical imaging system have a diagnostic quality, to correct viewing characteristics of the image such as orientation, rotation, contrast, as well as to add annotations to mark significant finding or provide guidance for radiologists.<br><br>OmegaAI Image Viewer can store annotations and measurements as DICOM presentation states without changing the original image data. OmegaAI Image Viewer can display annotations and measurements as an overlay on images from DICOM objects, and from Computer-Aided Diagnosis (CAD) and AI software. The viewer can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). OmegaAI Image Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and | | |

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| | reports side by side with the images. This can be used side by side with a reporting tool to create diagnostic reports.<br><br>**Note: To protect confidential information and ensure data security, the OmegaAI Image Viewer has User Access Control (UAC) which prevents unauthorized access and modification of data.**<br><br>**OmegaAI Image Viewer runs in a web browser sand-box, thus it relies on the browser's handling of interruptions, low-memory conditions etc. The browser will give an error to the user when it is not able to perform due to an interruption.**<br><br>**<u>Caution</u>: Federal law restricts this device to sell by or on the order of a physician.** | | |
| Intended Use | The OmegaAI Image Viewer is intended for diagnostic purposes and to be used as a review tool. | Primary diagnostic and review tool.<br><br>This software is not suitable for primary diagnosis of mammograms. | Nucleus.io is intended for diagnostic purposes and to be used as a review tool. |
| Image manipulation features | Adjustment Tools:<br>Window level, rotate, flip, pan, stack roll, and zoom.<br><br>Markup Tools:<br><br>Annotate, angle, cobb angle, probe, Mark ROI, and measurement. | Window/Level, Zoom, Rotation, Flip, Pan, Measure, and Annotation. RapidResultsdoes not produce or alter any images and medical data. | Window/level, flip/rotation, zoom, pan, measurement and Mark ROI. |

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| HIPAA Compliance | OmegaAI Image Viewer connects to the PACS using HTTPS.<br><br>OmegaAI Image Viewer does not store images on any user's device. Images are stored in the PACS, not on the device. When the web browser or mobile application is closed, all images and information are gone from the device. | The Viewer secured connects to the PACS using HTTPS Images stay in the PACS, not on the device. When the web browser or mobile application is closed, all images and information are gone from the device. RapidResults does not store images on any user's device. | Nucleus.io connects to the PACS using HTTPS.<br><br>Images are stored in the PACS, not on the device. When the web browser or mobile application is closed, all images and information are gone from the device. Nucleus.io does not store images on any user's device. |
| Support Modalities | View all image modalities, including CR, CT, DX, MR, MG, NM, US, PET, RG, SC, VL, XA, PET, and Film Digitizer. | View all image modalities, including X-ray, CT, MRI, color ultrasound and X-Ray angiography. | View all image modalities, including CR, CT, DX, MR, MG, NM, RF, US, and XA. |
| Architecture | Server-based software solution that displays images and reports from a PACS using a zero-footprint application (browser).<br><br>No installation is needed. | Server-based software solution that display images and reports from a PACS using a zero-footprint application (HTML5) | Server-based software solution that displays medical images and reports from a site's existing image archives (radiology, cardiology & other PACS and VNA systems), using a zero-footprint application (browser).<br><br>No installation needed. |
| Technology | Use of various technology standards (LDAP, SSO, HTTPS, HTML, HL-7 Integration web services, etc.) | Use of various technology standards (LDAP, SSO, HTTPS, HTML, HTML5, CSS, XML, web services, etc.) | Use of various technology standards (LDAP, HTTPS, HTML, HL-7 Integration web services, etc.) |
| Support Platforms, Devices | Supports major desktop (for diagnostic purposes) and mobile platforms (for non-diagnostic purposes; can be used as a review tool) such as | Support major desktop and mobile browsers such as Internet Explorer 10.0 or higher, Chrome, and Safari; on Apple iOS, Android, | Supports major desktop and mobile browsers such as Chrome, and Safari; on Apple iOS, Android, Windows Mobile devices. |
| | Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows and Mac devices. | Windows Mobile, and Black Berry devices. | |

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**Conclusion**

Based upon the 510(k) summary and 510(k) statement (21 CFR 807) and the information provided herein, we conclude that the subject device is sustainably equivalent to the predicate devices (Nucleus.io K203249 and Rapid Results K141881) under the Federal Food, Drug and Cosmetic Act.

**Software Validation and Verification Testing Summary**

The performance data provided in the form of test cases as well as validation test reports conducted on the OmegaAI Image Viewerinclude the following:

The verifications of features and major fixes were performed by members of the QA team. The verification of the product OmegaAI Image Viewer has been performed with the following steps

- Full regression tests have been executed on the build with the implementations of all major features. The purpose of this test phase is to uncover as much as possible all the potential bugs that could be detected by QA's test scripts. The "Full Regression" test plan is used during this testing cycle.

- Bug fix verification for reported issues and regression test on related features, "Quick Test" test plan is used during the test execution on the build: **5a5d485a7754cee49396e6084b884bfc4b7271b8**.

- Full regression tests have been executed on the candidate build for the release to verify all functionalities and fixes.

**Conclusion of Software Validation and Verification Testing**

Software Verification and Validation Testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." In conclusion, the OmegaAI Image Viewer is considered a "moderate" level of concern since a failure or latent flaw in the software could result in an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. This indicates that the subject device is sustainably equivalent to the predicate devices (Nucleus.io K203249 and Rapid Results K141881)