DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

RamSoft, Inc.
% Mr. Lely Lam-Hong
Director of Quality Assurance
243 College Street, Suite 100
TORONTO ON M5T 1R5
CANADA

Re: K141881
Trade/Device Name: RapidResults
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 29, 2014
Received: September 8, 2014

Dear Mr. Lam-Hong:

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

Janine M. Morris
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)*
K141881

Device Name
RapidResults

Indications for Use *(Describe)*

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 (on desktop platform) and non-diagnostic review tool (on mobile platform) for use by trained healthcare professionals. 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.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete 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 OMB number."*

# 510(k) Summary

**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

**General Company Information**

Company: RamSoft, Inc.
Contact: Lely Lam-Hong
Address: 243 College St, Suite 100, Toronto, ON M5T 1R5, Canada
Phone: +1-(416)-674-1347
Fax: +1-(416)-674-7147
Email: lhong@ramsoft.com

Date Prepared: June 30, 2014.

**General Device Description**

RapidResults is a cutting edge application that provides unseen levels of interactivity while maintaining the ease of use and security you've come to expect from RamSoft. Patient images and reports are available to view with zero footprint as there is no need to download special software. With RapidResults, the software allows users to perform image manipulations, including window/level, rotation, flip, zoom, panning, hanging protocol layout, measurement, localizer line, and study linking.

Available on popular mobile and desktop platforms with keyboard, mouse, and touch inputs, RapidResults provides access to medical images and associated documents in a convenient way for health care professionals to use as primary diagnostic and review tools.

RapidResults supports major desktop and mobile browsers such as Internet Explorer 10.0 or higher, Chrome, and Safari, Apple iOS, Android, Windows Mobile. It has been extensively tested with iOS (iPad Air, iPad Retina, iPad 2, and iPhone), Android (Galaxy Tab Pro, Galaxy Notes), Windows Mobile (Dell Latitude 10-ST2 Windows 8 Pro Tablet).

Common Name: Universal PACS Viewer
Trade Name: RapidResults
Classification: Class II, Produce Code LLZ

**Predicate Devices**

510(k) Number: K131977
Device Name: Centricity Universal Viewer Zero Footprint client (ZFP)
Company: GE Healthcare

**Indication for 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 (on desktop platform) and non-diagnostic review tool (on mobile platform) for use by trained healthcare professionals. 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.

**Comparison with the Predicate Devices**

| Characteristics | Subject Device | Predicate Devices |
|---|---|---|
| Device Name | RapidResults | Centricity Universal Viewer Zero Footprint client (ZFP) |
| Manufacturer | RamSoft, Inc. | GE Healthcare |
| 510(k) Number | K141881 | K131977 |
| Regulation Number, Class | 21 CFR 892.2050, Class II | 21 CFR 892.2050, Class II |
| Product Code | LLZ | LLZ |
| Indication for Use | This software displays medical images and associated documents.<br><br>With appropriate display monitors, lighting, image quality, and level of lossy image compression, the software is intended for use as a primary diagnostic (on desktop platform) and non-diagnostic review tool (on mobile platform) for use by trained healthcare professionals.<br><br>Each healthcare professional must determine if the level of loss is acceptable for their purpose.<br><br>This software is not suitable for primary diagnosis of mammograms. | Centricity Universal Viewer Zero Footprint client is a device that displays medical images, data from various imaging sources, and other healthcare information sources. Medical images and data can be viewed, communicated, processed and displayed within a computer network or on a workstation. The device may be used to provide images for diagnostic purposes by trained professionals.<br><br>Typical users of this system are authorized individuals and trained healthcare professionals who view medical images and data.<br><br>Mammographic images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies.<br><br>Contraindications:<br>Centricity Universal Viewer Zero Footprint client is contraindicated for the use of lossy |

| | | |
|---|---|---|
| | | compressed mammographic images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. |
| Intended Use | Primary diagnostic (on desktop platform) and non-diagnostic review (on mobile platform) tool<br><br>This software is not suitable for primary diagnosis of mammograms. | Use for the purpose of review, diagnostic interpretation and post-diagnostic review of medical images and reports. |
| Image manipulation features | Window/Level, Zoom, Rotation, Flip, Pan, Measure, and Annotation.<br><br>RapidResults does not produce or alter any images and medical data. | Window/Level, Zoom/Pan, Flip/rotate, Image<br><br>ZFP is a viewer that does not produce any original medical images nor does it alter any images or medical data. |
| HIPAA Compliance | The Viewer secured connects to the PACS using HTTPS<br><br>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. | ZFP is an HTML 5 based viewer which runs within a compatible web browser and supports secure transmission of data. |
| Support Modalities | View all image modalities, including X-ray, CT, MRI, color ultrasound and X-Ray angiography. | Single-frame and enhanced CT, MR, US, PT, XA, RF, SC Images<br><br>CR, DX, MG, IO, SC, XA, VL endoscopic, microscopic, and photographic image storage, slide coordinates microscopic image storage |
| Architecture | Server-based software solution that display images and reports from a PACS using a zero-footprint application (HTML5), no installation needed. | A zero-footprint application (HTML5) that retrieve and display images and reports from a PACS |
| Technology | Use of various technology standards (LDAP, SSO, HTTPS, HTML, HTML5, CSS, XML, web services, etc.) | The ZFP is a true HTML5 application that requires zero installation, and zero administrative rights required on the end user's device |



RamSoft Inc
243 College St, Suite 100, Toronto, ON M5T 1R5, CANADA

| | | |
|---|---|---|
| Support Platforms, Devices | Support major desktop and mobile browsers such as Internet Explorer 10.0 or higher, Chrome, and Safari; on Apple iOS, Android, Windows Mobile, and Black Berry devices. | A PC, Mac®, or an iPad® can be used with a variety of browsers |

**Conclusion**

Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is sustainably equivalent to the predicated devices (K131977) under the Federal Food, Drug and Cosmetic Act.