March 31, 2023

Imaging Wave, LLC
℅ Edward Kantor
President
7023 Juno Street
FORREST HILLS NY 11375

Re: K213660
Trade/Device Name: RadAlly™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 28, 2022
Received: January 4, 2023

Dear Edward Kantor:

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,

Yanna S. Kang -S For

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: 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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213660

Device Name
RadAlly™

Indications for Use *(Describe)*
RadAlly™ is a software Medical Image Management and Processing System (MIMPS) intended to transfer, display, archive, and review medical images in DICOM format for diagnostic use by a licensed practitioner, such as a radiologist or any physician maintaining the correct licensing criteria to read and interpret medical images. RadAlly™ supports multimodality imaging such as Ultrasound (US),
Digitized X-Ray Film (SC), Digital Radiography (DR), Computed Radiography (CR), Computed Tomography (CT), Magnetic Resonance (MR) Imaging. RadAlly™ is not intended for use with mammography – either film or full field digital mammography (FFDM) or tomosynthesis (Tomo or 3D Mammo). It is also not intended for use with nuclear medicine, PET, SPECT or CT fusion imaging.

RadAlly™ is not indicated for use on mobile displays. RadAlly™ may be interfaced with other DICOM modalities or MIMPS systems. All pertinent patient information may be displayed simultaneously. The viewer includes standard image measurement tools such as distance. RadAlly™ also includes manual measurement tools for use with ultrasound cardiac imaging, including Pressure-Half Time (PHT), Velocity-Time Integral (VTI), Aortic Valve Area (AVA) and Mitral Valve Area (MVA).

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.

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510(k) Summary

K213660

I. Submitter

Company: **Imaging Wave LLC**
Address: **7023 Juno Street**
Forrest Hills, New York 11375

Phone: **917-582-7761**

Contact Person: Edward Kantor
President

Date Prepared: **March 30, 2023**

II. Device

Trade Name: RadAlly™

Common or Usual Name: PACS / MIMPS

Classification Name: Medical Image Management and Processing System
(21 CFR 892.2050)

Class: II

Product Code: LLZ

Panel: Radiology

III. Predicate Device

Clear Canvas, cleared under K110332, Class II device
This product has not been subject to a recall.

IV. Device Description:

RadAlly™ is a software MIMPS designed to receive, archive, and display medical images. RadAlly™ offers viewing tools such as zoom, pan, magnification, and window/level. It also offers manual measurement tools including distance measure, angle, and ultrasound cardiology measurements including PHT, VTI, AVA, and MVA.

The user is intended to be a licensed practitioner, who uses the software to receive and view medical images as well as patient data.

The software is designed for use on the following operating systems: Windows 10 and higher, MAC 10.10 and higher. RadAlly is compliant with ACR/NEMA DICOM 3.1-3.20. The software product may be installed on any PC or Mac hardware which is capable of running the stated operating

systems. The hardware should include monitor, keyboard, mouse suitable for performing medical interpretation as stated for each modality by the ACR. The hardware must be web-enabled.

The device s self-contained software and is not bundled with any other device. It does not have any separable modules or additional options. RadAlly™ is the only model number.

RadAlly™ is software used to review medical images and patient information. It does not come into contact with patients, nor does it contain biologics or drugs. It is intended to be used to review multiple images sets. There are no coatings or additives. It does not require sterilization.

V. Indications for Use

RadAlly™ is a software Medical Image Management and Processing System (MIMPS) intended to transfer, display, archive, and review medical images in DICOM format for diagnostic use by a licensed practitioner, such as a radiologist or any physician maintaining the correct licensing criteria to read and interpret medical images. RadAlly™ supports multimodality imaging such as Ultrasound (US), Digitized X-Ray Film (SC), Digital Radiography (DR), Computed Radiography (CR), Computed Tomography (CT), Magnetic Resonance (MR) Imaging. RadAlly™ is not intended for use with mammography – either film or full field digital mammography (FFDM) or tomosynthesis (Tomo or 3D Mammo). It is also not intended for use with nuclear medicine, PET, SPECT or CT fusion imaging.

RadAlly™ is not indicated for use on mobile displays. RadAlly™ may be interfaced with other DICOM modalities or MIMPS systems. All pertinent patient information may be displayed simultaneously. The viewer includes standard image measurement tools such as distance. RadAlly™ also includes manual measurement tools for use with ultrasound cardiac imaging, including Pressure-Half Time (PHT), Velocity-Time Integral (VTI), Aortic Valve Area (AVA) and Mitral Valve Area (MVA).

RadAlly and the predicate device have the same intended use.

VI. Comparison of Technological Characteristics with Predicate Devices

RadAlly™ is a PACs / MIMPS type product as is the predicate device. Both products consist of receiving, archiving/storage and viewing capability for medical images and patient information. Both devices offer the same basic storage, viewing and receiving technology relying upon DICOM and other industry standards for format and operation. Both devices make use of the web for cloud support and storage systems. The feature set is fundamentally the same. Therefore RadAlly™ has been demonstrated to be as safe and effective as the predicate device for its intended use.

VII. Performance Data:

RadAlly™ has successfully undergone functional testing. Software verification and validation testing were 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." The software for this device was considered as a "moderate" level of concern.

Software verification and validation were performed to demonstrate the device performance. The measurements provided by the device were validated using bench testing against images with known measurements or through head-to-head comparison with the predicate device, when applicable.

The product has been shown to be equivalent to the predicate device. RadAlly™ was found to have a safety and effectiveness profile that is similar to the predicate device.

VII. Conclusions

RadAlly™ passed all Verification and Validation testing, which means that the features, functions and technology were all demonstrated to perform well. It uses the same technology, provides substantially the same functions, and is based on the same standards as the predicate device. RadAlly™ performs comparably to the predicate device which is currently marketed for the same intended use.