eVolve PACS Inc.
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
McKINNEY TX 75071

August 12, 2021

Re: K211863
Trade/Device Name: eVolve PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 27, 2021
Received: June 16, 2021

Dear Mr. Alletto:

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 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)*
K211863

Device Name
eVolve PACS

Indications for Use *(Describe)*

eVolve PACS, is a software device used for viewing and manipulating medical images and other healthcare related electronic records. Digital imaging units (including DR, CR, CT, MR, US, RF, and 2D/3D mammography), other computed and direct radiographic devices, secondary capture devices, document and film scanners, imaging gateways, other imaging devices and healthcare related electronic records can be displayed, processed, managed, stored and communicated across computer networks using this software.

eVolve PACS, can be integrated with a facility's existing Electronic Medical Records System (EMR), Hospital Information System (HIS), Practice Management System, Radiology Information System (RIS) and Dictation System. eVolve PACS, may also be integrated with the facility's Teleradiology Provider's systems. These integrations provide seamless operation and access for Providers and other caregivers to the entire spectrum of a patient's radiology records from the Provider's orders, to images of the exam, to completion data all the way to the interpretations (results/reports).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the eVolve PACS. Mammographic images may only be interpreted using an FDA cleared display that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by the FDA.
eVolve PACS is not intended for diagnostic review or other diagnostic uses on mobile devices.

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.

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510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submission number: K211863

I. SUBMITTER

Mr. David Donahue
Chief Financial Officer
eVolve PACS Inc.
3924 Bryn Mawr Drive, Dallas, TX 75225
Phone: 972.567.7300
Email ddonahue@xfinitisolutions.com

Date Prepared: June 3, 2021

II. DEVICE

Name of Device: eVolve PACS
Common or Usual Name: Regulation Name: Medical Image Management and Processing System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICES

The predicate device is: InstaRISPACS / InstaZFP / InstaMobi V5.0 (K182572), Class II, regulation number; 892.2050, product code LLZ.

IV. DEVICE DESCRIPTION

eVolve PACS, uses web-based technology and a secure operating system. This means that virtually any computer at any location can use an Internet browser to access eVolve PACS (and RIS) systems. Whether on-site or from another location, physicians can manage, edit, view and move diagnostic exams quickly and efficiently. As part of eVolve PACS support, eVolve PACS Inc., performs virtually all the system maintenance. eVolve PACS, has been designed to be expandable, with storage beginning at 2 TB and growing to 25 TB onboard or 256 TB expansion.

eVolve PACS is an implementation of an IHE (Integrating the Healthcare Enterprise) compliant Image Archive and Report Repository. This includes the capabilities:

- To store and retrieve various kinds of DICOM Objects such as:
  - Images from multiple modalities,
  - Grayscale Presentation States [GSPS], which specifies the presentations of images as gray scaling, zoom, text and graphical annotations,
  - Key Objects [KO], which specifies a particular selection of images for a specified reason and with an attached note,
  - Structured Reports [SR].
- To process HL7 notification messages from the Order Filler, about Procedure Scheduling, Procedure Updates and Patient Information Updates,
- To process DICOM Modality Performed Procedure Step [MPPS] messages from modalities and forward them to the Order Filler.

eVolve PACS is a server application. Its Web-based User Interface is intended for system configuration and monitoring by system administrators.

510(k) Summary

eVolve PACS, was developed with special emphasis on its telerad features for those facilities that use teleradiology either full time or for night reads.

Key Feature List

- Web-based technology for access from anywhere
- Integration with any modality, RIS, HIS or EMR via DICOM, HL7, desktop Integration, and custom integration
- Turnkey installations including all PACS professional services
- eVolve PACS, “off-site” disaster recovery service
- eVolve PACS, Net managed VPNs
- Transmission speed monitors and eVolve PACS, Track to monitor exams sent over the Internet
- eVolve PACS, Secure internal firewall and security features help prevent unauthorized access to the PACS
- Automatic management reports
- Detailed HIPAA log of all PACS transactions
- Exam scheduling
- DICOM editing
- DICOM modality worklist
- HL7 Interface engine
- Automatic radiology report distribution
- Diagnostic viewer
- CD burning with viewer
- Quick viewer with auto Cobb Angle calculation
- Accelerated transmissions
- eVolve PACS, Scan for document imaging
- eVolve PACS, eDOCS electronic forms to reduce scanning documents
- Pre-fetch
- Multiple worklists

The eVolve PACS, device does not intend to replace the skills and judgment of a qualified physician/radiologist and must be used only by people who are properly trained in the system’s functions and capabilities.

The User must be aware of the accuracy and precision limitations of the data displayed, printed or exported from eVolve PACS. The quality of these data depends on the information received, user interaction, and the features in the display device and printer, among others.

V. INDICATIONS FOR USE

eVolve PACS, is a software device used for viewing and manipulating medical images and other healthcare related electronic records. Digital imaging units (including DR, CR, CT, MR, US, RF, and 2D/3D mammography), other computed and direct radiographic devices, secondary capture devices, document and film scanners, imaging gateways, other imaging devices and healthcare related electronic records can be displayed, processed, managed, stored and communicated across computer networks using this software.

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eVolve PACS is not intended for diagnostic review or other diagnostic uses on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject and predicate devices are both medical image management and processing systems, which are indicated for medical image management, review, and data distribution. Both systems have been developed to replace traditional film handling in radiology. The subject device and the predicate device are substantially equivalent in the areas of general function, application, and intended use.

Any differences between the subject and predicate devices have no negative impact on the device safety or efficacy and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

Feature/Functions		**Subject Device – eVolve PACS**	**Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572**
System	Indications for Use	Medical image management and processing system	Medical image management and processing system
Workstation Client Hardware (recommended)	Processor	Intel Core i5	Core i7 / Quad Core Xeon
	Operating System	Windows 10 (64 bit)	Windows 8.1 (64 bit)
	Display	Medical Grade Monitor is recommended. Resolution depends on the modality type.	Medical Grade Monitor is recommended. Resolution depends on the modality type.
	RAM	Minimum 8GB RAM	Minimum 8GB RAM
	Hard Disk	500 GB	750GB minimum
Server features	System Architecture	Web based	Web based
	Hardware	Vendor Agnostic	Vendor Agnostic
	Security	Log-on user ID & password	Log-on user ID & password
	Remote monitoring	Yes	Yes
	Database	PostgresSQL	MySQLv5.7
Viewer Features:	Image Viewing Layout	Std. formats (up to 4*4)	Std. formats (up to 4*4)
	WW/WL	Yes	Yes

510(k) Summary

Feature/Functions		Subject Device – eVolve PACS	Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572
	Zoom in/Zoom out	yes	yes
	Hounsfield Measurement	Yes	Yes
	Linear and angle measurements	Yes	Yes
	Series Comparison	Yes	Yes
	Scout line display	Yes	Yes
	MPR/MIP capabilities	Yes	Yes
	Stack mode	Yes	Yes
	Gray scale invert	Yes	Yes
	Filters	Yes	Yes
	Rotate	Yes	Yes
	Key Image selection	Yes	Yes
	DICOM Print	Yes	Yes
	Windows print	Yes	Yes
	Query/Retrieve	Yes	Yes
	Image compression	Lossless streaming	Lossless streaming
	Selection tools	Thumbnails	Thumbnails
Reporting module	Reporting Interface	Can be opened from the from study list	Can be opened from the from study list
	Report Template Support	User Defined templates	User Defined templates
	Digital Signature	Yes	Yes
	Report Formats	MS office formats: PDF, rtf, text, Docx	MS word
Other features	Link to Hospital Information System (HIS)	Yes	Yes
	Link to Radiology Information System RIIS)	Yes	Yes
	Electronic patient record	Through Broker Software	Through Broker Software
	HIPAA	Compliant	Compliant
Configurations	PACS Server	Yes	Yes

510(k) Summary

Feature/Functions		Subject Device – eVolve PACS	Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572
	Radiology Workstation	Yes	Yes
	Basic Image Viewer)	Yes	Yes
	Mobile app viewer	Yes	Yes

VII. PERFORMANCE DATA

Clinical testing is not necessary to show substantial equivalence for the subject device. Successful Bench Testing should be sufficient in demonstrating substantial equivalence.

Nonclinical Testing:

The eVolve PACS, has been assessed and tested at the factory and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate output functions, and actions performed by eVolve PACS Inc. and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Summary:

Based on the performance as documented in the Validation Testing, eVolve PACS, was found to have a safe and effectiveness profile that is similar to the predicate device.

The following Standards were used to develop eVolve PACS, and the device has met all the requirements listed in the Standards except for inapplicable requirements:

Title of Standard	Date Of Recognition	Specialty Task Group Area	FDA Recognition Number	Standard Developing Organization	Standard Designation Number and Date
Digital Imaging and Communications in Medicine (DICOM) Set	06/27/2016	Radiology	12-300	NEMA	PS 3.1 - 3.20 (2016)
Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)	01/14/2019	Radiology	5-120	IEC	60812 Edition 3.0 2018-08,
Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	01/14/2019	Software/ Informatics	13-79	ANSI AAMI IEC	62304:2006/A 1:2016

510(k) Summary

- FDA Guidance on Cyber Security: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Document Issued on: October 2, 2014
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for eVolve PACS, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs comparably to the predicate devices.