Everrtech Software PVT LTD
Josh Baker
Consultant
A306 Western Edge II
Borivali East
Mumbai, 400066
India

April 10, 2024

Re: K232641
Trade/Device Name: Neorad Pacs (Neorad Pacs)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 11, 2024
Received: March 11, 2024

Dear Josh Baker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

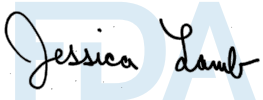
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232641

Device Name
NEORAD PACS (NEORAD PACS)

Indications for Use *(Describe)*
NeoRad 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.

NeoRad 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. NeoRad PACS, may also be integrated with the facility's Teleradiology Provider systems. These integrations provide seamless operation and access for Providers and other caregivers to the entire spectrum of 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 NeoRad 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.

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) #: K232641

510(k) Summary

Prepared on: 2024-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Everrtech Software PVT LTD
Applicant Address	A306 WESTERN EDGE II BORIVALI EAST MUMBAI 400066 India
Applicant Contact Telephone	714-788-8152
Applicant Contact	Mr. Josh Baker
Applicant Contact Email	josh@otconsulting.tech

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NEORAD PACS (NEORAD PACS)
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211863	eVolve PACS	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

NeoRad 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 NeoRad PACS systems. Whether on-site or from another location, physicians can manage, edit, view and move diagnostic exams quickly and efficiently. As part of NeoRad PACS support, Everrtech Software performs the system maintenance within its scope. NeoRad PACS, has been designed to be expandable, with storage beginning at 2 TB and growing to 25 TB onboard or 256 TB expansion.

NeoRad 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:

1. Images from multiple modalities,
2. Grayscale Presentation States, which specifies the presentations of images as gray scaling, zoom, text and graphical annotations,
3. Key Objects, which specifies a particular selection of images for a specified reason and with an attached note,

• To process HL7 notification messages from the Order Filler, about Procedure Scheduling, Procedure Updates and Patient Information Updates,

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

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

NeoRad 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.

NeoRad 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. NeoRad PACS, may also be integrated with the facility's Teleradiology Provider systems. These integrations provide seamless operation and access for Providers and other caregivers to the entire spectrum of 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 NeoRad 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject and predicate device indications for use are the same. 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.

Technological Comparison

21 CFR 807.92(a)(6)

Both the subject and predicate devices are software as a medical device. Any differences are due to improved technology or up-revision from the 3rd party applications between the predicate and the new device and has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The NeoRad 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 Everrtech Software PVT LTD 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.
FDA Guidance on Cyber Security: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Document Issued on: October 2, 2014
FDA Guidance on Content of Premarket Submissions for Device Software Functions Document Issued on: June 14, 2023

Not Applicable

The non-clinical testing demonstrates that the subject device performs in accordance with its intended use, complies with the requirements specified in the FDA-recognized consensus standards, and meets the acceptance criteria indicating that the subject device does not raise any new safety and/or effectiveness concerns and is substantially equivalent to the predicate.