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 14, 2016

Novarad Corporation
% Mr. Doug Merrill
Regulatory and Compliance Manager
752 East 1180 South, Suite 200
AMERICAN FORK UT 84003

Re: K160371
Trade/Device Name: NovaPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 26, 2016
Received: September 26, 2016

Dear Mr. Merrill:

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

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)*

K160371

Device Name
NovaPACS

Indications for Use *(Describe)*

NovaPACS is intended for the viewing, archiving, analysis, annotation, registration, distribution, editing, fusion, and processing of digital medical images and data acquired from diagnostic imaging devices and all DICOM devices, etc.

NovaPACS is intended for use by trained healthcare professionals, including radiologists, physicians, technologists, clinicians, and nurses. NovaPACS allows the end user to display, manipulate, archive, and evaluate images.

Mobile devices are not intended to replace a full workstation and should be used only when there is no access to a workstation. They are not to be used for mammography. Mobile devices are used for diagnosis of medical images from different modalities including CT, MR, US, CR/DX, NM, PT, and XA. For a list of compatible mobile platforms see NovaPACS Diagnostic Viewer User Manual.

While NovaPACS full workstation provides tools to assist the healthcare professional determine diagnostic viability, it is the user's responsibility to ensure quality, display contrast, ambient light conditions, and to confirm image compression ratios are consistent with the generally accepted standards of the clinical application.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter

Novarad Corporation

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Phone: 801-642-1001

Contact Person: Doug Merrill

Date Summary Prepared: 4 February 2016

Device Name

Trade Name: NovaPACS

Common Name: PACS

Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K132853	NovaPACS	Novarad Corporation
K103785	Mobile MIM	MIM Software Inc. (formerly MIMvista Corp.)

Indication for Use

NovaPACS is intended for the viewing, archiving, analysis, annotation, registration, distribution, editing, fusion, and processing of digital medical images and data acquired from diagnostic imaging devices and all DICOM devices, etc.

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from different modalities including CT, MR, US, CR/DX, NM, PT, and XA. For a list of compatible mobile platforms see *NovaPACS Diagnostic Viewer User Manual.*

While NovaPACS full workstation provides tools to assist the healthcare professional determine diagnostic viability, it is the user's responsibility to ensure quality, display contrast, ambient light conditions, and to confirm image compression ratios are consistent with the generally accepted standards of the clinical application.

Device Description

NovaPACS is a picture archiving and communication system software that retrieves, archives, distributes, and displays images and data from all common modalities. NovaPACS uses a variety of workstations, including a Technologist Workstation, Enterprise Radiologist Workstation, Cardio Viewer and Workstation, NovaMG Workstation, and NovaWeb Web Viewer. NovaPACS uses a variety of mobile platforms and browers including iPad 2 (Safari Browser), Nexus 7 (Chrome Browser), and iPad mobileRAD (Native Application). For a list of possible browser choices for one platform that are valid for diagnostic viewing see *NovaPACS Diagnostic Viewer User Manual.*

The NovaPACS software makes images and data available in digital format from all common modalities. The images are viewed on a computer monitor or portable device. NovaPACS tools/features include the following: window, level, zoom, pan, digital subtraction, ejection fraction, cross localization, note-taking ability, voice dictation, and other similar tools. It includes the capability to measure distance and image intensity values, such as standardized uptake value. NovaPACS displays measurement lines, annotations, regions of interest, and fusion blending control functionality. Advanced features include 3D image rendering, virtual colonoscopy,virtual fly-through, time domain imaging, and vessel analysis.

Images and data are stored on a digital archive with multiple redundancies; images and data are available on-site and off-site. Novarad provides all software, including third party software (i.e. Windows® OS). NovaPACS software resides on third party hardware, which may vary depending on the client's PACS needs. All hardware is connected to the radiology department local area network.

NovaPACS integrates with NovaRIS and may integrate with any other third party RIS software that has HL7 interface capabilities.

NovaPACS integrates with Novarad Mobile Rad application and web viewers to display data on 3rd party mobile platforms. Mobile devices are not intended to replace full workstation and should be used only when there is no access to a workstation. They are not to be used for mammography.

Substantial Equivalence

Research and testing data provide evidence that NovaPACS is substantially equivalent to the represented predicate devices: NovaPACS, a class II device under 21 CFR 892.2050; and MobileMIM, a class II device under 892.2050.

NovaPACS and all predicate devices are Radiological Image Processing Systems which retrieve, store, and display images from DICOM compliant medical imaging modalities and/or systems. All are intended to be used in healthcare settings, such as hospitals and clinics, on 3rd party off-the-shelf hardware, and connected to a local area network. All

are intended to provide qualified medical professionals with a variety of tools and software features for the viewing, analysis, and annotation of medical images.

The new version of NovaPACS for which this submission is provided is an upgraded version of the predicate NovaPACS device. The new version of NovaPACS software differs from the NovaPACS predicate software in intended use by auto-detecting unsupported mobile platforms at HTML5 login to display a persistent on-screen message of "Not for diagnostic viewing". Although this feature was not available in the previous version of NovaPACS, this similar feature is already available in other predicate devices.

Performance testing results show that the software features of NovaPACS operate correctly and safely and meet equivalent objectives and perform equivalent functions as those represented in the predicate devices. Performance testing also shows that the unique combination of safety features represented in NovaPACS does not raise any additional safety concerns.

Bench Testing

Mobile display performance testing was performed in accordance with the description and requirements described in the AAPM Assessment of Display Performance for Medical Imaging Systems (April 2005) document by a third party testing facility to ensure high quality laboratory results. The test equipment and calibration was certified traceable to NIST. Testing measured contrast response and evaluated test patterns for geometric distortions, resolution, noise, non-uniformity, viewing angle, luminance response, specular reflectance, and diffuse reflectance according to TG18 guidelines.

The specific results regarding the measured luminance from the mobile devices with respect to the target luminance response using JND plots was provided to the FDA.

Clinical Testing

Clinical testing was conducted independently by a panel of three board certified radiologists in the United States. The radiologists conducted a comparative evaluation of the Native App (mobileRad), IOS, Android, and Windows mobile device platforms running NovaPACS with the predicate NovaPACS workstation. Each radiologists followed the same criteria of instructions to ensure the study was standardized. For each study the radiologist individually rated the contrast, sharpness, artifact and overall quality as either acceptable or unacceptable in comparison to the predicate NovaPACS workstation. Testing was conducted using six typical cases for each imaging modatlity including CT, MR, US, CR/DX, NM, PT, and XA on each mobile device. Comparative results of image quality and diagnostic assurance were made by each radiologist.

Each radiologist agreed that the Native App (mobileRad), IOS, Android, and Windows mobile devices were comparable to the predicate NovaPACS workstation across all seven modalities and of adequate quality for clinical use. They were comfortable with the diagnosis made on the mobile devices using the NovaPACS software. All agreed that the overall clinical image display quality on the Native App (mobileRad), IOS, Android, and Windows mobile devices were equivalent to the NovaPACS workstation for the identification of clinically relevant details.

Each radiologist indicated that the software and mobile devices provide acceptable quality for regular use and they were satisfied reviewing images on the mobile devices.

Each radiologist agreed that the same diagnosis would be made on the mobile devices with NovaPACS as on the predicate NovaPACS workstation in low lighting conditions, office lighting conditions, and in bright light conditions.

Performance Testing

Thorough software testing has been performed for NovaPACS to safety and efficacy of the device. Of over 1200 test cases run on the NovaPACS Software, 99% passed, 1% failed, and 0% were blocked on their latest run. Of the failed tests, the majority represent minor user interface errors. We believe that the testing performed so far is sufficient to conclude that the features and functionality of NovaPACS software is substantially equivalent to that of the predicate devices, and that it does not raise any new safety concerns.

Verification and validation activities are performed on NovaPACS during software development prior to release, and in an ongoing manner for any updates. NovaPACS software passes all performance requirements and meets all specifications prior to release, including:

a. All requirements in the iteration have a test case and the test case has run and passed
b. All Acceptance tests have passed
c. All Current tests have passed
d. All high-impact bugs have been corrected and verified by Quality Assurance
e. Any unresolved anomalies have been assessed in a risk meeting, and it has been found that they do not pose a safety risk to the end user (or their patients) and do not substantially affect the performance of NovaPACS software.

Verification and validation includes functional usability across three mobile platforms; Native App (mobileRad), IOS, and Android.