K063153

510K Summary

NovaRad Corporation

DEC - 7 2006

NovaRad Corporation, located at 758 E. Utah Valley Dr., Ste 200 in American Fork, UT 84003 is submitting its PACS product. The contract person is Paul Shumway. The name of the device is PACS. It is a class 2 device under 892.2050. The trade name is NovaPACS.

This device is being represented as substantially equivalent to the Kodak DirectView (Carestream) PACS product, a class 2 device under 892.2050. The PACS product provides a system where images and accompanying data are sent from the modalities to the radiologists and technologists in digital format. The images are then viewed on a computer with such available tools a window, level, zoom, pan, roi, digital subtraction, ejection fraction, cross localize, and many other similar tools and with the ability to make notes and dictate a report. The images and report are then stored long term on a digital archive with multiple redundancy. All the information is also made available as a web based product where referring physicians or radiologists can access the information from anywhere using a secure system. The software is provided by NovaRad along with some 3rd party software, principally from windows, and resides on off-the-shelf hardware hooked up to the radiology department local area network.

The general use of this device is to be used to read images and information from modalities and store this data so that it can be easily retrieved.

As compared to the predicate device, ignoring dissimilarities of hardware brand and specific tools, menus, shortcuts, usability, desktop appearance, price and data base type, the products are exactly similar. The both provide the exact same ability to replace film with digital and they both perform the exact same functions. Both products could be used interchangeable in most aspects. When a customer is looking at our product compared to the predicate device, they are mostly considering differences in service level, price, and ease of use.

There are no clinical tests to compare the two as they are merely software products that send and store images and information. Since the images are not changed or analyzed by the product there is no safety issue, except possible related to the safety of the archived images. NovaRad has more redundancy than the predicate device in that they store the original images on-site with a redundant RAID 5 configuration and then they have another RAID 5 archive on site as a redundant archive and then NovaRad stores a 3rd multiple redundant copy of each image and accompanying information at its corporate headquarters.

Although NovaRad is only a PACS with all the customary tools and features of any other major PACS, the reader may wish to glance at the accompanying brochure to gain a sense of what the product looks like.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Paul Shumway
Vice President
NovaRad Corporation
758 East Utah Valley Drive, Suite 200
AMERICAN FORK UT 84003

DEC - 7 2006

Re: K063153
Trade/Device Name: NOVAPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 21, 2006
Received: November 21, 2006

Dear Mr. Shumway:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications of Use

NovaRad Corporation

October 9, 2006

892.2050, class II

The product being submitted is going to be used as a PACS system and provide viewing tools for radiologists, technologists, other physicians, cardiologists, and patients. It will also provide archiving of images and data. The product will be sold to hospitals, imaging centers, and clinics. It is a software product sold with accompanying off-the-shelf hardware. It is substantially equivalent to other products now being sold as PACS. Further it is for using DICOM for presentation of Mammography studies, not for image processing. Will include the standard features for Mammo of window/level/zoom, as well as volumetric measurements and other Mammo tools. Mammo will only be interpreted on 510K approved 5 Mp LCD monitors. The Mammo images will be stored lossless (non-lossy compressed). Digitized conventional screen film mammograms will not be used in soft copy format for primary diagnosis.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063153