K101796

510(k) Summary

[As required by section 807.92(c)]

1. Submitter:
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2. Official Correspondent:
   Tom Chen (Mr.)

JUL 15 2010

3. Date of 510(k) Submittal: 6. January, 2010

4. Device Trade Name
   PACSmate MMD-5201M monitor

5. Common Name: LCD monitor

6. Classification Name:
   System, image processing, radiological [were classified in class II (21 CFR 892.2050)]

7. Device Product Code:
   LLZ

8. Predicate Device:
   Manufacturer: EIZO NANAO CORPORATION
   Device name: 5 Megapixel monochrome LCD monitor
   Model name: RadiForce GS520
   510(k) No.: K080422

9. Device Description:
   The MMD-5201M LCD monitors are displays for medical use. MMD-5210M provides 5 mega pixel resolution and 766 grayscales per pixel display. The display device is complied with the standard ISO13406-2 to conform to the requirement of the mammography display system.

10. Intended Use:

The device is intended to be used as a tool in displaying and viewing digital images, including digital mammography system for view and analyses by trained medical practitioner.

11. Technological Characteristics:

The PACSmate MMD-5201M is a high performance, 5 Megapixel medical grade monochrome LCD monitors designed for exacting needs for diagnostics professionals that provide clear and sharp images with resolutions of up to 2560 x 2048 pixels, up to maximum 850 cd/m^2 brightness and 600:1 contrast ratio, making it ideal for diagnosing detailed medical graphics. Also uses a DVI digital interface offering compatibility with the latest digital standards. The technical specification is compliance with the ISO 13406-2 standard: ergonomic requirements for flat panel displays ergonomics.

12. Performance Testing:

The performance test results for the PACSmate LCD monitor demonstrated that the device meets its intended use specifications and therefore meets the requirements necessary for its intended use as a displayer for medical image.

13. Substantial Equivalence to Predicate Device:

PACSmate MMD-5201M is substantially equivalent to RadiForce GS520. MMD-5201M employs the maximum resolution values same as that of RadiForce GS520. Comparison table of the principal characteristics of two devices is shown in the Section II and specification data for the use of mammography system monitor is included in Section I.

14. Conclusion:

In terms of intended use, construction, function, safety, operating environmental conditions, and effectiveness of the PACSmate MMD-5201M monitor is substantially equivalent to the predicate device used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

IEI Technology Corporation
% Mr. Marc M. Mouser
Manager & FDA Office Coordinator
Underwriters Laboratories, Inc.
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CAMAS WA 98607-8542

JUL 15 2010

Re: K101796
Trade/Device Name: PACSmate MMD-5201M monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 17, 2010
Received: June 28, 2010

Dear Mr. Mouser:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not known~~ K101796

Device Name: PACSmate MMD-5201M monitor

Indications for Use:

The device is intended to be used as a tool in displaying and viewing digital images, including digital mammography system for view and analyses by trained medical practitioner.

Prescription Use ___√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

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