510(K) Summary K102148

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Contact: Deepak Sharma, Managing Director
Date prepared: August 12, 2010

AUG 17 2010

1. Trade Name: CuriePACS Dicom PACS Software
   Common Name: PACS Software
   Classification Name: System, image processing, radiological

2. Regulation Description Picture archiving and communications system, product code LLZ, Regulation: 892.2050 Class of device: Class II.

3. The legally marketed device to which we are claiming equivalence Voyager PACS System, Voyager Imaging, K062062.

4. Description of device: CuriePACS is a comprehensive solution for Dicom imaging needs. This scalable PACS solution provides electronic viewing, storage and communication in a secure environment. The device consists of: 1. Dicom Server (MD Athena) – For storage and connectivity with all the modalities and 2. Image Viewer (MD Vision) – To connect to the server and retrieve images based on search criteria and other workflow requirements. Image modalities supported: CR, CT, DX, MG, MR, NM, RF, SC, US, XA (x-ray) , and ES.

5. Indications for use: CuriePACS (Dicom PACS Software) Software is a software device that receives digital images and data from various sources (Computed Radiography, Magnetic Resonance Imaging, Ultrasound, Endoscopy, Computed Tomography, Digital X-Ray Mammography, Nuclear Medicine Imaging, Secondary Capture, Radio Fluoroscopy, X-Ray or other Angiograms such as CT Angio). Images and data can he captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.

6. Technological characteristics: The software is installed on a network connected PACS server with the following minimum requirements:

   - Microsoft® Windows® XP Service Pack 2 or above
   - Microsoft® Windows® Vista Service Pack 1 or above
   - Microsoft .Net Framework 3.5 SP1
   - Microsoft Internet Explorer 7 or above
   - Intel Core 2 Duo Processor
   - 320 GB HDD

- 2 GB RAM (Min)
- Dedicated or Onboard Graphics card with minimum 1440 x 900 resolution and DVI output.
- Gigabit Ethernet Adaptor
- Display: The display used for diagnosis purposes should be FDA approved self calibrating medical grade monitor which is driven by a digital input (DVI output from graphics card).

7. **Comparison Table**

Characteristic	**Predicate Device Voyager PACS System, Voyager Imaging, K062062**	**CuriePACS (Dicom PACS Software) (This submission)**
Indications for Use	Voyager PACS System is a software based dev ice that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices. secondary capture dev ices, scanners, imaging gateways, etc.). Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.	CuriePACS (Dicom PACS Software) Software is a software device that receives digital images and data from various sources (Computed Radiography, Magnetic Resonance Imaging, Ultrasound, Endoscopy, Computed Tomography, Digital X-Ray Mammography, Nuclear Medicine Imaging, Secondary Capture, Radio Fluoroscopy, X-Ray or other Angiograms such as CT Angio). Images and data can he captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.
Use, key feature	Medical professionals, WEB based	SAME
Connection	WEB and Ethernet	SAME
Multimodality Connectivity, DICOM compatibility	Voyager PACS can receive with ease any DICOM compliant image, irrespective of the source	Connect all DICOM Modalities CR, CT, DX, MG, MR, NM, RF, SC, US, XA (x-ray) , and ES.
Image Sources	Dicom, JPEG and JPEG 2000 compliant	SAME
Target hardware	PC compatible	SAME
Image Processing Tools	• Brightness/ Contrast • Mouse button operation for quick image manipulation • Selectable multiple image view• Magnify, zoom and pan• Flip (left/ right, top/bottom) and rotate• Image inversion • Measurement and angles	All processing tools Stack, Window/Level, Zoom, Pan, Magnifying Glass, Probe, Spatial Locator, Draw Shutter, Ruler, Elliptical ROI, Rectangular ROI, Polygonal ROI, Text Area, Text Callout, Protractor.
Security	SSL Encryption	SAME

8. Performance: The results of nonclinical tests submitted showing Dicom 3 compliance, along with bench testing (software validation and risk analysis) shows that this new device has equivalent indications and performs in an equivalent fashion to the named predicate. Therefore this device poses no new issues of safety or effectiveness, and is substantially equivalent to the predicate device.

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

Moksha Digital Software PVT Limited
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 17 2010

Re: K102148
Trade/Device Name: CuriePACS (Dicom PACS Software)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2010
Received: July 30, 2010

Dear Mr. Job:

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

K102148

Indications for Use

510(k) Number (if known): K102148.

Device Name: CuriePACS (Dicom PACS Software)

Indications For Use:
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Prescription Use _X_ 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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