

Indications for Use

510(k) Number (if known): _____
Device Name: dicomPACS® 5.2 / dicomPACS® DX-R 1.6

Indications for Use:

dicomPACS® and **dicomPACS® DX-R** are software systems for the administration, archiving, processing, improvement and compression of medical image data for diagnosis. The images are either acquired from imaging modalities via DICOM or imported directly. All images are archived in a database as DICOM compliant files. The data is displayed on a computer monitor for diagnosis. **dicomPACS®** and **dicomPACS® DX-R** also provides services for administering the data.

dicomPACS® DX-R can control X-ray generators. **dicomPACS® DX-R** is not approved for the acquisition of mammographic image data.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Functions to be carried out using **dicomPACS®** and **dicomPACS® DX-R** are, for example, but not limited to, adjustment of window leveling, rotation, zoom, and measurements.

dicomPACS® and **dicomPACS® DX-R** are meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.

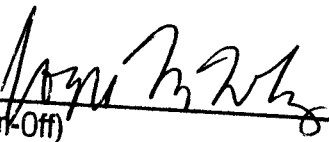
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091364