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)*
K141561

Device Name
VM PACS with VM Medical Workstation

Indications for Use *(Describe)*
VM PACS is designed to Store Medical Dicom Images and leave them available to be used for diagnostics or transferred to other Dicom devices.

VM PACS is not meant to create or modify DICOM images. VM PACS store the images and the Data Set send by an DICOM compatible image diagnostic equipment and store them making them available to be access by a workstation or viewer, or been transfer to another Dicom Compatible device.

VM PACS does not modify the images store in it.

User Graphic interface VM Medical Workstation is a complete Workstation which provides diagnostic tools for image diagnose, for CT, MR, PT, CR, DX, NM, MG, XA, RF, SC, US and ES, as zoom, Window & Level variation and presets, measurements and a complete set of diagnostics tools and includes a report tool for the studies.

Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

VM Clinical Viewer is the web access interface of VM PACS, which allows integration with any Operating System, brings to the institution the capacity to access the images remotely.

VM Clinical Viewer allows the specialist consultation and the communication between radiologists and referring physicians. The system enables authorized external users to have access to specific patient studies, is not intended for diagnostic purposes when used on mobile devices.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.