

K051809

Device Name: Medical Insight, EasyViz™ PACS System

Indications For Use:

The Medical Insight EasyViz™ PACS System is a Diagnostic Softcopy Reading software package to be used for primary diagnosis and clinical review of digital radiology images.

The product utilizes the conventional TCP/IP internetworking infrastructure available in most healthcare organizations, and it uses commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows XP, Linux).

The product interfaces to existing imaging equipment using the DICOM PS 3.1-2000 (Digital Imaging And Communications In Medicine) standard communication protocol as described and developed by ACR.

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 M-pixel resolution and meets other technical specifications reviewed and accepted by the US FDA.

The system does not permanently store or produce original medical images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 901.109)

OR

Over-the-Counter Use

*David A. Johnson*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K051809

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FDA Indication for Use Form