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510(k) Summary
[as required by 21 CFR 807.92]

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Submitter's Information [21 CFR 807.92(a)(1)]

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Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade name is Fuji Computed Radiography FCR/DICOM Gateway Unit CR-DM 666.

The device common name is DICOM Gateway.

Predicate Device [21 CFR 807.92(a)(3)]

Fuji views the subject device as an accessory to the predicate device, the Fuji FCR DMS Optical Disk Image Filing Unit OD-F6X4/L Series. FDA assigned the predicate to regulatory class II citing 21 CFR § 892.1750.

FDA's accession number for the premarket notification for the predicate device is K960326. FDA cleared the marketing of the predicate device in a letter dated March 7, 1996.

Description of the Device [21 CFR 807.92(a)(4)]

The device consists of a computer (console, display, keyboard, and mouse) and software. The device connects Fuji's proprietary Data Management System (DMS) medical image data network to networks complying with the American College of Radiology (ACR) and National Association of Electrical Manufacturers (NEMA) Digital Imaging and Communications in Medicine (DICOM) standard.

The Fuji network may contain Fuji Computed Radiography (FCR) image readers, workstations, optical disk files, multiformatters, and hard copy image printers. The multiformatters may receive image data from other modalities such as ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI).

The FCR/DICOM Gateway Unit CR-DM666 is a DICOM CR-Storage Service Class (SCU) and DICOM SC-Storage Service Class device.

Intended Use [21 CFR 807.92(a)(5)]

The indications for use of the FCR/DICOM Gateway Unit CR-DM666 is to serve as a gateway between a proprietary FCR DMS network and a standard ACR/NEMA Digital Imaging and Communications (DICOM) network.

Technological Characteristics [21 CFR 807.92(a)(6)]

There device does not contact the patient, nor does it control any life sustaining devices. Images crossing the gateway are interpreted by a physician, providing ample opportunity for competent human intervention.

The subject and predicate devices are both based on an industry-standard Sun SPARC Station with 64-bit micro-SPACR II microprocessor, standard 64MB RAM, and 1.5 GB fixed magnetic disk storage. Both use a CRT for character display as part of the user interface. No image data is displayed.

Unlike the predicate, the subject device may perform simple image processing: image rotation, reversal, and the decompression of reversibly compressed (ratio: ½) image data. No compressed image data is sent to the DICOM network.

Data loss may occur because of hardware failure (e.g. hard disk crash) or operator error (e.g. turning off power during hard disk access). However, unlike the predicate, as the device is not the data source, the gateway transmission can be completed after correcting the cause of the failure. Operation is password protected to prevent unauthorized use.

Performance Data [21 CFR 807.92(b)(1)]

The subject and predicate devices both use standard data communications controls to detect and correct errors.

The device complies with the UL 1950 *Standard for Safety of Information Technology Equipment, Including Electrical Business Equipment.*

Conclusion [21 CFR 807.92(b)(3)]

As is the case with the predicate, the subject device have no patient contact. Nor do the subject device control, monitor, or effect any devices directly connected to or effecting a patient. The images relayed by the subject devices are observed by medical personnel, offering ample opportunity for competent human intervention in the event of a failure.

The device functions as a communications protocol converter, and not as a permanent image store. Device failures which might result in a failed transmission may be recovered from by retransmission after correcting the problem. Passwords are required for operation to protect against unauthorized use.

The subject and predicate share the same certification of conformance to the UL 1950 *Standard for Safety of Information Technology Equipment, Including Electrical Business Equipment.*

We conclude that the subject devices are as safe and effective as the predicate device.