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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 Medical Laser Imager MF Print Server MF-PS667.

The device common name is Print Server, Network Print Server.

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

Fuji identifies the subject device as an accessory to the predicate device, the Fuji Medical Laser Imager Multi-Formatters MF-300 and MF-300L. FDA assigned the predicate to regulatory class II citing 21 CFR § 892.1000 (magnetic resonance diagnostic device).

FDA's accession number for the premarket notification for the predicate device is K950721. FDA cleared the marketing of the predicate device in a letter dated May 24, 1995.

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 a DICOM or Toshiba medical image data network to Fuji hard copy printing systems.

The network typically carries images from modalities (e.g. CT, MR, NM, or US) or other image sources being transported under DICOM or Toshiba network protocol. The print server accepts the image data, performs protocol conversion to Fuji's protocol, and passes it to Fuji's hard copy print system.

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

The indication for use of the Fuji Medical Laser Imager MF Print Server MF-PS667 is to connect imaging modalities on a network to a hard copy system for hard copy output.

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

The device does not contact the patient, nor does it control any life sustaining devices. Images crossing the print serve 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-SPARC 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: 1/2) 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, the device is a data source or image archive, 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 IEEE802.3 standard transceiver for Ethernet connection is employed. 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 DICOM standard communications protocol converter, and not as a permanent image store. Standard communications error detection and correction methods are employed. Standard network interface connections are employed. 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.