

SEP 12 1997

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

Date Prepared [21 CFR 807.92(a)(1)]

June 13, 1997

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

Fuji Medical Systems U.S.A., Inc.
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Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 (for Networks)
- FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 Multimodality Display System

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

FDA classified the predicate FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 with the FDA product code IXK as a regulatory class II medical device "System, Imaging, X-ray, Electrostatic", citing 21 CFR § 892.1630 "Electrostatic X-ray Imaging System" under 510(k) K931002. Under FDA's proposed rules (61 FR 63774 of December 2, 1996) Fuji believes FDA would classify this device as Class II, 21CFR 892.2050 "picture archiving and communications system".

FDA's accession number for the premarket notification for the predicate device is K931002. Fuji received notifications that FDA cleared the marketing of the predicate device in a letter dated June 8, 1993.

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

The subject device consists of a computer (system unit, display, keyboard, and mouse) and software. The subject device is a software modification of the predicate device. The modification may be to either existing or newly-installed predicate devices. One of two software modifications may be installed:

- 1? The network software adds network communication capability and newly permits lossy compression/decompression of approximately 5:1, 12:1, or 20:1. A "transmitter" network HI-C654 is connected directly to an image reader and can transmit images which optionally have undergone lossy compression to a network. A "receiver" network HI-C654 is connected only to the network and can

receive images from the network. The transmitter/receiver status is indicated at power-on. Lossily compressed images are so labeled on the CRT display, along with a compression code which indicates the approximate compression rate. See page XXX.

2? The multimodality software a) includes the capabilities of the network software above, and b) adds the ability to receive images from multiformatters

3? The subject device connects either directly to one or two FCR® image readers, or to a proprietary network. The network may have on it FCR® image readers and Fuji multiformatters with image data from other imaging modalities such as CT, MR, DSA, NM, for example.

The device receives images from the FCR® image reader or network and stores, process, and displays the image. Stored images may be transmitted to other devices, such as multiformatters, printers, archiving units, or other CRT image consoles.

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

The indication for use of the FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 Multimodality Display System for Networks is to receive, process, display, and transmit medical images.

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

The device does not create image data, does not contact the patient, nor does it control any life sustaining devices. Images displayed on the CRT image console are interpreted by a physician, providing ample opportunity for competent human intervention.

The subject device is a software modification of the predicate. No new hardware issues are raised.

The device newly permits (optional) lossy data compression and decompression. Three irreversible compression types are available with approximate compression rates of: 5:1, 12:1, and 20:1. A single compression type is set by service personnel for each device and cannot be modified by the user. Adjacent to every lossily compressed image, the soft label "irreversibly compressed" is displayed on the CRT along with an indication of the approximate compression ratio. The effects on image quality of irreversible compression and decompression are discussed in the operation manual.

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, as the device is not the data source nor image archive, the data can be recovered by requesting a retransmission from the other host modalities (CT, MR, US, NM) or optical disk filing equipment after recovering from a failure. Operation is password protected to prevent unauthorized use. The software does not allow access to the link between image and relevant patient ID information preventing patient image mix-ups.

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 has 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.

Irreversibly compressed and decompressed images are so labeled along with an indication of the compression type. Standard communications error detection and correction methods 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.



SEP 12 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Robert A. Uzenoff
Fuji Medical Systems U.S.A., Inc.
333 Ludlow Street
P.O. Box 120035
Stamford, CT 06912-0035Re: K972256
FCR® Fuji Computed Radiography DMS CRT Image
Console 41-C654 Multimodality Display System For Networks
Dated: June 13, 1997
Received: June 16, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

Dear Mr. Uzenoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 10(k) Number (if known): K972256

Device Name: Fuji Medical Laser Imager MF Print Server MF-PS667

Indications For Use:

The indication for use of the FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 Multimodality Display System for Networks is to receive, process, display, and transmit medical images.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

David M. Seymour
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972256

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)