JUN 25 1999

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

Date Prepared [21 CFR 807.92(a)(1)]
April 9, 1999

Submitter's Information [21 CFR 807.92(a)(1)]
Fuji Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT. 06902
Telephone: (203) 602-3677
Facsimile: (203) 327-6485
Contact: Joseph Azary

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

The device trade name is Fuji wavelet compression or FFCOMP irreversible compression. The device common name is medical image communication device or wavelet compression software.

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

FDA classified the predicate FCR® Fuji Computed Radiography DMS CRT Image Console HI-C654 Multimodality display system for networks with FDA product code LLZ as unclassified (before medical device communication devices were put into class I) under 510(k) number K972256. Fuji received notification that FDA cleared the marketing of the predicate device in a letter dated September 12, 1997.

Fuji is aware of other medical devices on the market that utilize irreversible compression such as:

- PICTools Medical Compression Toolkit K982146
- Kodak Digital Science™ Medical Image and Information Library K972380

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

The subject device is a software product that consists of algorithms that perform irreversible wavelet compression on data found in digital medical images. This software may be used with current Fuji products (such as the Synapse™ Image & Information Management System, Fuji workstations) or future medical image communication or PACS devices.

The subject device has three user-configurable modes of operation; 1) Base Line Mode, 2) Fast Decomp Mode-1 (semi-high speed), and 3) Fast Decomp Mode-2 (high speed).

For further details on the Fuji Wavelet compression Algorithm, see the product description in Annex 1, as well as the quantitative test results in Annex 2.

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

Fuji wavelet compression is intended to be used in applications to compress digital medical image data.

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

The device does not contact the patient, nor does it control any life sustaining devices. This device is used for the compression of data in digital medical images. The physician makes the choice whether to subject the digital medical images to irreversible compression. The labeling informs of the user of possible effects on image quality. Additionally, the image will include a displayed message to inform the observer whether it has been subjected to irreversible compression and what type and ratio. The images are interpreted by a physician, providing ample opportunity for competent human intervention.

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

There are no performance standards applicable to the subject device have been issued under authority of section 514 of the Food, Drug, and Cosmetic Act.

However, representatives from Fuji are active participants on the committee that is developing JPEG-2000. The Fuji wavelet compression is one of the candidates to the JPEG-2000 proposal.

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

As is the case with the predicate devices, the subject device has no patient contact. Nor does the subject device control, monitor, or effect any devices directly connected to or effecting a patient.

The physician makes the choice whether it is appropriate to subject the digital medical images to irreversible compression. Irreversibly compressed images are so labeled along with an indication of the compression type and ratio. Standard communications error detection and correction methods are employed. Images subjected to irreversible compression, by the subject device, are observed by medical personnel, offering ample opportunity for competent human intervention in the event of a failure.

We conclude that the subject device is as safe and effective as the predicate device and poses no new questions for safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

Joseph Azary
Regulatoory Affairs Coordinator
Fuji Medical Systems, Inc.
419 West Avenue
Stamford, CT 06902

RE: K991257
Fuji Wavelet Compression or FFCOMP
Irreversible Compression
Dated: April 12, 1999
Received: April 13, 1999
Regulatory Class: II
21 CFR 892.2050/ Procode: 90 LLZ

Dear Mr. Azary:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA 510(k) Premarket Notification
Fuji wavelet compression

510(k) Number (if known): K991257

Device Name: Fuji wavelet compression

Indications For Use:

Fuji wavelet compression is intended to be used in applications to compress digital medical image data.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991257

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)