K02 2658

SEP 6 2002

510(k) Summary

LR DICOM Controller

Common/Classification Name: Medical Image Hard Copy Device
21 CFR 892.2040

Agfa Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Jeff Jedlicka; Prepared: August 9, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The predicate device is the LR 5200 Printer and Controller, which was cleared originally by FDA on 5 November 1996 as K964414 and also with clarified indications on 27 June 2001 as K012010.

B. DEVICE DESCRIPTION

The modification involves replacing the controller function of the currently marketed MG3000 component of the LR5200 system so that a new controller can transmit image information from an Ethernet to the LR 5200 at up to 100 MB/sec. The communications board in the LR5200 will also be modified to accept the new communications approach. The MG3000 will still be used in some applications, e.g., to interface a non-networked imaging modality directly to the LR 5200, or to interface a non-DICOM modality to a network.

C. INTENDED USE

The LR DICOM Controller is a part of the LR 5200 Laser Film Recorder system, which is indicated for use in providing diagnostic quality medical images on film for aid in physician diagnosis, including the printing of images from various digital imaging source modalities, including, but not limited to, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound, Computed Radiography, Digital Mammography, and Nuclear Medicine.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The modified **LR 5200 Printer/Controller** has the same indications for use as the legally marketed predicate device. The modified device

has the same technological characteristics as the currently marketed device. This premarket notification will describe most of the characteristics of the modified **LR DICOM Controller** in sufficient detail to assure substantial equivalence. For the few characteristics that may not be precise enough to ensure equivalence, performance data or certifications are provided.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices.

F. TESTING

The modified **LR DICOM Controller** has been tested for proper performance to specifications through various in-house reliability and imaging performance demonstration tests.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Mr. Jeff Jedlicka
Manager of Regulatory Affairs
Agfa Corporation
10 South Academy Street
Mail Stop 100
GREENVILLE SC 29601

Re: K022658
Trade/Device Name: LR DICOM Controller
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: August 7, 2002
Received: August 9, 2002

Dear Mr. Jedlicka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K02 2658

Device Name: LR 5200 Laser Film Recorder with LR DICOM Controller

Indications For Use:

The LR 5200 Laser Film Recorder is indicated for use in providing diagnostic quality medical images on film for aid in physician diagnosis, including the printing of images from various digital imaging source modalities, including, but not limited to, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound, Computed Radiography, Digital Mammography, and Nuclear Medicine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Hegman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022658

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)