SEP 2 0 2001

510(k) Summary

LR 5200 Laser Film Recorder

K012010
page 1 of 2

Classification Name: Medical Image Hard Copy Device
21 CFR 892.1140

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

Contact: Jeff Jedlicka, Prepared: June 20, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

The LR5200 was cleared for marketing through the premarket notification K964414 on January 27, 1997. The LR5200 with revised indications for use statement is substantially equivalent to the currently marketed LR 5200.

B. DEVICE DESCRIPTION

No changes in hardware or software are being implemented to the currently marketed LR5200. The present 510(k) is only for a clarification in the indications for use. The **LR5200** is a laser (He-Ne) film recorder designed to produce high quality gray scale diagnostic medical images when interfacted to a host imaging device or PACS system. The **LR5200** uses a wet process for developing the medical images.

C. INTENDED USE

The present LR5200 is currently indicated for the printing of digital medical images and it is also currently indicated for printing of images from several specific imaging modalties, including mammography. The clarification to the indications for use will make it explicit that the device is indicated for the printing of digital mammography images.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **LR 5200 Laser Film Recorder** is a medical device, and it has very similar indications for use as the legally marketed predicate device. The **LR 5200 Laser Film Recorder** has the same (identical) technological characteristics as the predicate device. This premarket notification has described the characteristics of the **LR 5200 Laser**

Film Recorder in sufficient detail to assure substantial equivalence.[1]

E. TECHNOLOGICAL CHARACTERISTICS

No changes in hardware or software are being implemented to the currently marketed LR5200, so the technological characteristics are identical.

F. TESTING

No additional testing was carried out for this premarket notification since the device is already indicated for the same uses.

G. CONCLUSIONS

This 510(k) has demonstrated substantial equivalence to the predicate device.

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[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Agfa Corporation
% T. Whit Athey, Ph.D.
Senior Consultant
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Suite 625
ROCKVILLE MD 20850

Re: K012010
Trade/Device Name: LR 5200 Laser Recorder
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical Image Hard Copy Device
Regulatory Class: II
Product Code: 90 LMC
Dated: June 27, 2001
Received: June 27, 2001

Dear Dr. Athey:

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): K012010

Device Name: LR5200 Laser Film Recorder

Indications For Use:

The LR5200 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)

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012010