K023287

OCT 22 2002

510(k) Summary

Drystar 5500
Dry-Process Medical Image Printer

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: September 30, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

On April 27, 2001, FDA cleared the Drystar 4500 printer under 510(k) number K010275. The **Drystar 5500**, the subject of the present Special 510(k), is a modification of the currently marketed Drystar 4500. In hardware, software, and intended use, the **Drystar 5500** is substantially equivalent to the Drystar 4500.

B. DEVICE DESCRIPTION

The Drystar 5500 is a dry-process, B/W printer, using the direct thermal printing principle to establish continuous-tone images with medical diagnostic image quality. The printer has two film input trays and each can accept any of five sizes of film, 8x10, 10x12, 11x14, 14x14, and 14x17. Film may be loaded in full daylight. The printer is a network-only printer.

The resolution of both the Drystar 4500 and 5500 is 506 dpi. The print head in the Drystar 5500 is 14 inches wide (compared to 10 inches in the 4500), which with constant resolution means more pixels per line for the 5500.

The film for the Drystar 5500, DT2 B/C, allows for faster printing (up to 180 films per minute for the largest size film) than the TM1 B/C used with the Drystar 4500.

C. INTENDED USE

The **Drystar 5500** is a free-standing printer used to print diagnostic images on transparent film for viewing on a standard view box. It may be

used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Drystar 5500** is a medical device and it has the same indications for use as the legally marketed Drystar 4500. The **Drystar 5500** has the same technological characteristics as the Drystar 4500, and this premarket notification has described the characteristics of the **Drystar 5500** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the **Drystar 5500** are qualitatively identical to those of the predicate device, the Drystar 4500. The Drystar 5500 and its DT2 film represent enhancements of the same basic design.

F. TESTING

The Drystar 5500 will be certified for electrical safety according to EN 60601-1-1 and UL-2601, and electromagnetic compatibility according to EN 60601-1-2.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(I)(1) of 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

OCT 22 2002

Mr. Jeffery A. Jedlicka
Manager, Regulatory Affairs
and Compliance
AGFA Corporation
10 South Academy Street
Mail Stop 100
GREENVILLE SC 29601

Re: K023287
Trade/Device Name: Drystar 5500
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: September 30, 2002
Received: October 2, 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 3287

Device Name: Drystar 5500

Indications For Use:

The **Drystar 5500** is a free-standing printer used to print diagnostic images on transparent film for viewing on a standard view box. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable.

(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)

/s/ Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023287