K023020

SEP 2 6 2002

510(k) Summary

Agfa Film Cassettes

Common/Classification Name: Radiographic Film Cassette, 21 CFR 892.1850

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

Contact: Jeff Jedlicka, Prepared: August 21, 2002

A. INTRODUCTION

There are three product lines of Agfa Film Cassettes covered by the present 510(k): (1) The Mamoray Mammography Cassettes, (2) the metal-bodied CAWO Cassettes, and (3) the ABS Plastic Curix and Lightweight Cassettes. The present submission describes the currently marketed products by cassette type and shows that they are substantially equivalent to cassettes currently marketed in the U.S.

B. PREDICATE DEVICES

The Agfa Mamoray Mammography Cassettes are substantially equivalent to the Agfa Mammography Cassettes, which were cleared for marketing by FDA on March 21, 1979 as K790273. The Agfa Metal-Bodied CAWO Cassette is substantially equivalent to the Kodak X-Omat Cassette, which was cleared for marketing by FDA on March 1, 1989 as K890750. The Plastic Curix and Lightweight Cassettes are also substantially equivalent to the Kodak X-Omat Cassette.

C. INTENDED USE

The Agfa Film Cassettes are indicated for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a lightproof enclosure for direct exposure of radiographic film.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Agfa Film Cassettes** have the same indications for use statement compared to those of the legally marketed predicate devices. The Agfa Film Cassettes have the same technological characteristics as the predicate devices. This premarket notification will describe the

characteristics of the Agfa Film Cassettes in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Agfa Film Cassettes are the same as those of the predicate devices.

F. STANDARDS

The Agfa Film Cassettes are designed and manufactured to meet the requirements of ANSI/NAPM 1.49-1995, DIN 6832, Parts 2 and 3; and IEC 406.

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 2 6 2002

Agfa Corporation
c/o R. Kent Donohue
Underwriters Laboratories, Inc.®
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709-3995

Re: K023020
Trade/Device Name: Agfa Film Cassette
Regulation Number: 21 CFR §892.1850
Regulation Name: Radiographic film cassette
Regulatory Class: II
Product Code: 90 IXA
Dated: September 10, 2002
Received: September 11, 2002

Dear Mr. Donohue:

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): K013020

Device Name: Agfa Film Cassettes

Indications For Use:

The Agfa Film Cassettes are indicated for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a lightproof enclosure for direct exposure of radiographic film.

(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)

David A. Segarra

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013020