K981280

APR 30 1998

## SECTION 1

## 510(k) SUMMARY

Agfa's Automatic Film Processor product family is designed for the intended use of processing standard medical x-ray, laser, and video types of imaging films. These would be used in all radiographic imaging modalities including but not limited to Ultrasound, X-Ray, Nuclear Medicine, Computed Tomography, Mammography, Cardiology, and Magnetic Resonance.

All currently marketed automatic film processors have the same basic components, including a feed and detection mechanism, a processing system consisting of chemical tanks and transport racks, a washer, a dryer, a receiving bin, and controls and indicators. Major subsystems include water supply, temperature regulation, chemical replenishment, and solution circulation.

The device performs standard photographic processing of previously exposed sheets or rolls of silver-halide based films. The processed films contain acquired anatomical images for viewing by physicians, typically of the radiological discipline specialty. The photographic processing (developing) technique employed by these automatic processors is the same as all devices manufactured by several companies, and has gone basically unchanged in approximately fifteen years. The film medium is mechanically transported for immersion in two chemical baths (developer and fixer), is rinsed in water, dried, and then ejected for viewing and archival purposes.

The Agfa family of automatic film processors also offers additional operational features such as daylight handling and processing, laser film recorder docking, and automatic film handling for various types and sizes of imaging films used in the above radiographic applications. Some models offer the E.O.S. (Environmentally Optimized System) feature. This feature employs an additional fixer tank technique that reduces fixer solution consumption and waste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Michael Sullivan
AGA Division, Bayer Corporation
Official Correspondent
100 Challenger Road
Ridgefield Park, NJ 07660-2199

Re: K981280
CP1000, Curix HT 330, Classic E.O.S.,
Curix HT 530, Mamoray HT 300
Dated: April 5, 1998
Received: April 8, 1998
Regulatory class: II
21 CFR 892.1900/Procode: 90 IXW

Dear Mr. Sullivan:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**SECTION 3**

**PRESCRIPTION DEVICE**

Indications For Use:

To process (develop) medical imaging films for viewing by physicians. This may be used in the imaging modalities of Ultrasound, X-Ray, Nuclear Medicine, Computed Tomography, Mammography, Cardiology, and Magnetic Resonance.

M. Sullivan

Michael Sullivan
Official Correspondent

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Concurrence of CDRH, Office of Device Evaluation

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981280

Prescription Use ✓ OR Over –the-Counter Use _____
(Per 21 CFR 801.1090 (Optional Format 1-2-96)