

K973125

Department of Health and Human Services  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Pre-Market Notification Section

OCT - 8 1997

Date: August 1, 1997

**510(k) Summary of Safety and Effectiveness for the**

**MAMMOLOADER by C.M.A. srl, Via S. Andrea 23, 40064 Ozzano Emilia,  
Bologna Italy**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The MAMMOLOADER will be used to unload and or load medical imaging films from the KODAK Mammography film cassettes (18x24 cm & 24x30 cm) and KODAK Video Film Holder (8x10 in), under roomlight conditions.

Typical users of this system are trained medical professionals, including but not limited to physicians, nurses and lab technicians.

The undersigned certifies that the 510(k) Pre-Market Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence to the KODAK X-OMAT Multiloader 300 (K905607). This information and data is summarized as follows:

1. The MAMMOLOADER system is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.
2. The MAMMOLOADER system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.  
(UL-122 photographic equipment, IEC 380, IEC 801-4, IEC 801-3, EN 55014 E POST, EEC 87/308 EMI regulations, and EN 60950 electrical safety.)
3. The MAMMOLOADER Operator Guide contains comprehensive and extensive information on how to operate the system to ensure a safe and effective use.
4. The submission contains the results of a hazard analysis.



Mr. Massimo Azzaroni  
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Bologna Italy  
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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 8 1997

Mr. Massimo Azzaroni  
Director  
C.M.A. srl  
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40064 Ozzano Emilia  
Bologna Italy

Re: K973125  
MAMMOLOADER by C.M.A. srl (Room light, cassette loader/  
un-loader)  
Dated: August 1, 1997  
Received: August 20, 1997  
Regulatory class: II  
21 CFR 892.1900/Procode: 90 IXW

Dear Mr. Azzaroni:

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 requirement, 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/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

510(k) Number:

Device Name: MAMMOLOADER

Indications For Use:

The MAMMOLOADER is a device designed to unload and or load medical imaging films from the KODAK Mammography film cassettes (18x24 cm & 24x30 cm) and KODAK Video Film Holder (8x10 in), under roomlight conditions.

Two versions are available; integrated with a medical imaging film processor so that when film cassettes are unloaded the film is sent directly into the film processor, or in a stand-alone version in which exposed films are unloaded from cassettes and placed into a receive magazine for processing at a later time.

Typical users of this system are trained medical professionals, including but not limited to physicians, nurses and lab technicians.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division of ENT,  
Division of ENT,  
and Radiology  
510(k) Number

Prescription Use   
(Per 21 CFR 801.109)

OR Over -The-Counter Use

David A. Bergerson  
(Division of ENT,  
Division of ENT,  
and Radiology  
510(k) Number K973125

(Optional Format 1-2-96)