

JAN 25 1999



K984252

Imation Corp.
1 Imation Place
Oakdale, MN 55128-3414
612 704 4000 phone
800 537 4675 fax

510(k) Summary

Nov 25, 1998

Imation Corp.
1 Imation Place
Oakdale MN 55128-3414

Contact: Stephen G. Slavens
1 Imation Way
DIS-4B-75
Oakdale MN 55144-3414
Phone: 651-704-3536
FAX: 651-704-4469

Device:	Trade name:	Imation™ Trimatic™ Digital System
	Common name:	PACS System
	Classification name:	Image Processing System LLZ 21 CFR 892.2020 Class II

Predicate device:

The Imation™ Trimatic Digital System is comprised of cleared or exempt devices with the exception of the digitizer, which is identical to the digitizer in clearance (K982785) except for minor film feeding hardware and communication software.

Description and Intended Use of Device:

The Imation™ Trimatic™ Digital System is intended for use as a system to convert radiographic films into a digitized format for use in a hospital or other clinical image management system. The digitized image receives patient and exam information and is then forwarded into a DICOM compliant image management system. The digitizer has the resolution capable of faithfully digitizing standard and mammographic x-rays.

Technological Characteristics:

The Imation™ Trimatic™ Film Digitizer uses a laser scanner to scan and digitize the film image. The digital image has 12 bit image depth and is in Dicom 3.0 format. The scan rate and spot size are adjusted depending on the film type to accurately capture either 5 or 10 line pairs per mm for standard and mammographic films, respectively.

Performance Data:

Voluntary standards used in the design of the subject device(s) are:

UL1950		Safety of Information Technology Equipment
21 CFR1040		Laser Safety Standards
IEC825		Laser Safety Standards
EN60601-1-2 Class A		Electro-Magnetic Compatibility
EN55011	1991-97	Radiated and Conducted Immunity
EN55014-1	1993-97	Conducted Immunity
EN61000-4-2	1995	Electro-Static Discharge
EN61000-4-3	1996	Radiated Radio-frequency
ENV 50204	1995	Immunity to RF Telephone Emissions
EN61000-4-4	1995	Electronic Fast Transfer
EN61000-4-5	1995	Surge
EN61000-4-6	1996	Conducted immunity
EN61000-4-8	1993	Power Frequency Magnetic Field
EN61000-4-11	1994	Power Line Fluctuation

Conclusion:

The Imation™ Trimatic™ Digital Imaging System has no patient contact, does not control or monitor patient medical status. Digital images generated by the Trimatic Digital System are interpreted by competent medical practitioners, offering ample opportunity for competent human intervention where warranted.

Imation believes the subject device is safe and effective based on comparison to the predicate device, on prior clearance of devices incorporated in this system and by conformance to the above design standards.



JAN 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Stephen G. Slavens
Regulatory Affairs Manager
Imation Corp.
1 Imation Place
Oakdale, MN 55128-3414Re: K984252
Imation™ Trimatic™ Digital System
Dated: November 25, 1998
Received: November 27, 1998
Regulatory class: II
21 CFR 892.2030/Procode: 90 LMA

Dear Mr. Slavens:

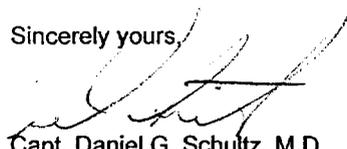
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Statement of Indications for Use:

510(K) Number (if known): K984252

Device Name: Imation™ Trimatic™ Digital System

Indications for Use:

The Imation™ Trimatic™ Digital System is intended for use as an automated system to convert radiographic films into a DICOM format image for use in a hospital or other clinical Image Management System (IMS). The digitizer has the resolution capable of faithfully digitizing standard and mammographic x-ray films.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David L. Beggs
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984252