

K962750

AUG 21 1996



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

510(k) Summary

July 1, 1996

Imation Corp.
1 Imation Place
Oakdale MN 55128

Contact: Stephen G. Slavens
3M Center, 235-2B-23
St. Paul MN 55144-1000

Phone: 612-736-9536
FAX: 612-736-3116

Device:

Trade name: 3M Trimatic™ Advanced Processing System
3M APS Automatic Film Processor

Common name: Modular x-ray film loading system with integrated
automatic film processor

Classification name: Modular film loader / unloader - Unknown
Automatic radiographic film processor -
21 CFR 892.1900 - Class II

Predicate Device:

3M Trimatic™ M Plus Daylight System - (510(k) K880565, 21 March
1988)
3M XP 515 X-Ray Film Processor (510(k) K880563, 21 March 1988).

Description and Intended Use of Device:

The 3M Trimatic™ Modular Advanced Processing System is an automatic, modular system for unloading exposed x-ray film from x-ray film cassettes, processing the film, and reloading the empty x-ray film cassette with fresh x-ray film of the same size and type. The 3M Trimatic™ Modular APS will accommodate from four to seven different film types / sizes in film modules. This system is used for handling and processing of x-ray films from all general radiographic, diagnostic procedures which employ conventional x-ray film / screen technology. 3M Trimatic™ Modular APS

provides remote diagnostic capability. The integrated automatic x-ray film processor can also be used as a stand-alone processor.

The 3M Trimatic™ Modular APS can be fit with a “through-the-wall-kit” which will enable it to accept film from a darkroom.

Technological Characteristics:

Both the subject device and the predicate use mechanical rollers, guides and drives and pneumatic means to move the x-ray film within the device. The subject device has moved and altered some of the internal mechanisms to reduce the size of the film magazine modules. The integrated automatic x-ray film processor in the subject device uses mechanical rollers and guides, chemical replenishment and chemical agitation methods which are similar to the predicate processor.

The software used to control the operation of the subject device has added capabilities over the software used in the predicate device. Encoded in the bar codes on the x-ray film cassettes are the x-ray film size, type and the correct processing conditions for that particular film. This information drives the operation of the device. Remote diagnostics via phone line is also an added feature in the subject device.

The control panel controls both the load / unload process and the automatic x-ray film processor. The predicate device has separate controls for each operating section of the device.

Performance Data:

Voluntary standards include:

UL 122

IEC 950

IEC 801-2, 3, 4, 5

EN 55011

3M Trimatic™ APS Engineering Specification (Part B)

With the successful conclusion of both the field test and internal qualification / validation tests the software final release must be approved by the product team for production. After final approval, according to established procedures, the software label code will change to the production label.