K972822

510(k) Summary

NOV 19 1997

July 28, 1997

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
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Device:

Trade name:	Imation™ SE-204 Laser Imager
Common name:	Laser Printer
Classification name:	Magnetic Resonance Diagnostic Device 21 CFR 892.1000

Predicate devices: 3M(Imation™) 8300 Laser Imager(K936152)
Agfa LR 5200 Laser Film Recorder(K964414)

Description And Intended Use of Device:
The Imation™ SE-204 laser imager is intended use as a high resolution hard copy device for output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the SE-204 and transformed optically to expose Imation imaging media. The system is intended for use with a variety of digital modalities, including, but not limited to Digital Radiography and full view digital mammography for diagnostic use by medical radiologists and communications to referring physicians and their patients.

Technological Characteristics:
The subject device and predicate devices use the same technical design base. The printers receive image data from the modality. Modality data and printing functions are performed by the IMS(Image management System). User control is performed by a keypad or directly by the modality through the host control. Imation imaging media is removed from a daylight cartridge and transported to the laser imaging station. Image data and media merge at the laser station and the film is scanned. The exposed media is transported through the integrated processor and exits the printer.

Software is used to control the image management and machine functions. AIQC(Automated Image Quality Control) matches printing power with film characteristics to provide consistently high image quality.

Performance Data:
An important performance characteristics for medical hard copy devices is spatial resolution. The subject and the predicate Agfa devices are similar with respect to spatial resolution with SE-204 pixels giving slightly higher dpi.

Safety and effectiveness are assured via meeting voluntary standards, including IEC601-1, IEC601-1-1, IEC601-1-2, UL2601 and Imation™ SE-204 Engineering specification(Part B).

With the successful conclusion of both the field test and internal tests for qualification, validation and reliability, the Product Team will approve final release for production (including Software). After final approval, according to the established procedures, the software code label will be changed to production level label.

Conclusion:
The subject device, like the predicates, has no patient contact. The devices also do not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Images displayed by the subject device and its predicates are reviewed by medical personnel, offering ample opportunity for competent human intervention in case of a malfunction or other failure.

The subject and predicate device DryView™ Model 8300 have both been designed to the same safety standard. As with this predicate device, a test pattern generator and automatic image quality control(AIQC) system are incorporated to assure consistency between input signals and output density. The subject device has been designed to have similar resolution as the predicate Agfa LR 5200 Laser Film Recorder, which has the indications for use of full view digital mammography and high resolution computed radiography.

Imation therefore concludes that the Imation™ SE-204 Laser Imager is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1997

Steven G. Slavens
Regulatory Affairs Manager
Imation Enterprises Corporation
3M Center, Bldg. 235-2B-23
St. Paul, MN 551441000

Re: K972822
Imation SE-204 Laser Imager
Dated: October 18, 1997
Received: October 21, 1997
Regulatory class: Unclassified
Procode: 90 LMC

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 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,

William Yin

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

ATTACHMENT 2

Statement of Indications for Use:

510(K) Number (if known):_____

Device Name: Imation™ SE-204 Laser Printer

Indications for Use:

The Imation™ SE-204 laser imager is intended use as a high resolution hard copy device for output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the SE-204 and transformed optically to expose Imation imaging media. The system is intended for use with a variety of digital modalities, including, but not limited to Digital Radiography and full view digital mammography for diagnostic use by medical radiologists and communications to referring physicians and their patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Clinton A. Jessmon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972822