

510(k) Summary

K972163

SEP - 5 1997

June 1, 1997

Imation Corp.
1 Imation Place
Oakdale MN 55128

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

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Device: Trade name: Imation™ SE-196 Laser Imager
Common name: Laser Printer
Classification name: Magnetic Resonance Diagnostic Device
21 CFR 892.1000

Predicate devices: 3M(Imation™) 8700 Laser Imager

Description And Intended Use of Device:

The Imation SE-196 Laser Imager provides high quality hard copy film output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the SE-196 and transformed optically to expose Imation imaging media. The system is intended for use with a variety of digital modalities including CT, MR and CR 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:

Important performance characteristics for medical hard copy devices are spatial frequency response, gray scale resolution and density information. The subject and predicate devices are similar with respect to spatial frequency response with pixel size of both devices being 325 dpi. Gray scale resolution for the predicate is wither 8 or 12

bit and 12 bit only for the subject device. Density uniformity of the subject device is the same or better than the predicate device. Both devices have built in density test patterns and AIQC (Automatic Image Quality Control) that maintains density uniformity over time and over changes in the film media.

Safety and effectiveness are key activities in the commercialization and are assured via meeting voluntary standards, including UL544, IEC601-1, IEC 825 and Imation™ SE-196 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 effect any devices directly connected to or effecting 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.

Films imaged by the subject device display the same or better image properties in the areas of spatial and gray-scale resolution and in density uniformity as the predicate. As with the predicate devices, a test pattern generator and automatic image quality control(AIQC) system are incorporated to assure consistency between input signals and output density.

The subject and predicate device(s) have all been designed to the same safety standard, UL1950.

Imation therefore concludes that the Imation™ SE-196 Laser Imager is as safe and effective as the predicate device



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Stephen G. Slavens
Regulatory Affairs
Imation Corp.
1 Imation Place
Oakdale, MN 55128-3414

Re: K972163
Imation™ SE-196 Laser Imager
Dated: June 1, 1997
Received: June 9, 1997
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,

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): K972163

Device Name: Imation™ SE-196 Laser Printer

Indications for Use:

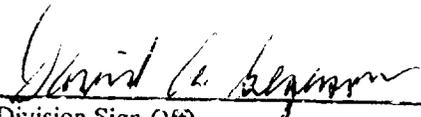
The Imation™ SE-196 laser imager is intended use as a high quality hard copy device for output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the SE-196 and transformed optically to expose Imation imaging media. The system is intended for use with a variety of digital modalities including CT, MR and CR for diagnostic use by medical radiologists and communications to referring physicians and their patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972163