K973033

510(k) Summary

Sept 2, 1997

NOV 25 1997

Imation Corp.
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Contact: Stephen G. Slavens
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St. Paul MN 55144-1000

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Device:	Trade name:	Imation™ MODEL 9410 NETWORK INTERFACE
	Common name:	PACS Communication Device
	Classification name:	Medical Image Digitizer (Proposed) 21 CFR 892.2030 (Proposed)

Predicate devices: Cemax-Icon Scanlink V and Merge MVP

Description And Intended Use of Device:
The Imation™ MODEL 9410 NETWORK INTERFACE Network Interface is intended for use as a communications gateway. It accepts input from imaging source modalities and transfers the image data to a compatible printing, viewing, archive or network system. The MODEL 9410 NETWORK INTERFACE accepts input in DICOM standard, digital or video formats and converts, if needed, to DICOM Standard or other digital formats. The system is intended for use with a variety of imaging modalities including CT, MR and CR for the transmission of image data to a variety of printing, viewing and storage devices.

Technological Characteristics:
The subject device and predicate devices use the same technical design base. The communications gateway devices receive image data from an imaging modality. User control is performed by a keypad or directly by the modality through the host control. Based on the control data from the modality, image information is transferred to the appropriate destination device.

Software is used to convert, as needed, image and control data from one digital format to another. In the case of analog video digitization, a commercially available video frame grabber / digitizer board is used.

Performance Data:

Safety and effectiveness are key activities in the commercialization and are assured via meeting voluntary standards, including UL950, CSA C22.2 No. 950, and Imation™ MODEL 9410 NETWORK INTERFACE Requirements specification(Part B).

Released software, according to the established procedures, is given a production level code and subsequent code changes undergo testing, hazard analysis and approval equivalent to the initial release.

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 communicated 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.

Images communicated by the subject device maintain the same or better image properties in the areas of spatial and gray-scale resolution and in density uniformity as the predicate. No lossy compression is used in this device.

The subject and predicate device(s) have all been designed to equivalent safety standards.

Imation therefore concludes that the Imation™ MODEL 9410 NETWORK INTERFACE Network Interface is as safe and effective as the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Imation Corporation
c/o Stephen G. Slavens
3M Center, 235-2B-23
St. Paul, MN 55144-1000

Re: K973303
Imation ™ Model 9410 Network Interface
Dated: September 2, 1997
Received: September 3, 1997
Regulatory class: Unclassified
Procode: 90 LMD

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): K973303

Device Name: Imation™ MODEL 9410 NETWORK INTERFACE Network Interface

Indications for Use:

The Imation™ MODEL 9410 NETWORK INTERFACE Network Interface is intended for use as a communications gateway. It accepts input from imaging source modalities and transfers the image data to a compatible printing, viewing, archive or network system. The MODEL 9410 NETWORK INTERFACE accepts input in DICOM standard, digital or video formats and converts, if needed, to DICOM Standard or other digital formats. The system is intended for use with a variety of imaging modalities including CT, MR and CR for the transmission of image data to a variety of printing, viewing and storage devices.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David C. Seyson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973303