510(k) Summary of Safety and Effectiveness

K973413

Submitter:	ISG Technologies, Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa, Clinical Scientist
Telephone:	(905) 672-2100
Date:	September 8, 1997
Trade Name:	ID.Store
Common Name:	Picture Archiving and Communication System (PACS) component software.
Classification Name:	PACS: Image Storage Device.
Predicate Device:	Kodak Medical Image and Information Library (MIIL).
Device Description:	The ID.Store device is a software package composed of several application modules which work in tandem using a distributed storage architecture to control the archival storage and retrieval of digitized medical images. The ID.gate (gateway), ID.store (archiving), and ID.dbs (image database manager) modules communicate with each other using the dedicated administrative communication protocol ImageTalk. Permanent archival storage media supported include CD-R, WORM, MOD/WORM, DVD, etc. Recommended hardware are standard general purpose equipment, e.g. Sun Sparc or UltraSparc CPU's, and RAID devices for temporary data storage.
Intended Use:	ID.Store is a software device intended to direct the lossless archival storage and retrieval, including the use of pre-fetching and auto-routing capabilities, of digital medical images within a Picture Archiving and Communications System (PACS).
Comparison to Predicate:	The intended use and technological characteristics of the ID.Store device are substantially equivalent, in the opinion of ISG Technologies, to those of the predicate device and do not pose any additional issues of safety and effectiveness.

NOV 25 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Carol Nakagawa
Clinical Scientist
ISG Technologies, Inc.
6509 Airport Road
Mississauga, Ontario
Canada L4V 1S7

Re: K973413
ID. Store (PACS Component Software)
Dated: September 8, 1997
Received: September 9, 1997
Regulatory class: Unclassified
Procode: 90 LMB

Dear Ms. Nakagawa:

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

510(k) Number (if known): K973413

Device Name: ID.Store

Indications For Use:

ID.Store may be used for the permanent storage and subsequent retrieval of any medical imaging data presented in DICOM or other supported format, within a Picture Archiving and Communications System (PACS).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973413

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

(Optional Format 1-2-96)