DEC 21 1998

510(k) Summary

K982535

1. Company Identification

Neo Imagery Technologies, Inc.
2315 S. Birch Log Way
Hacienda Heights, CA 91745
Tel. (626) 333-3633
Fax (626) 961-0080

2. Official Correspondent

Gary J. Allsebrook
Regulatory Affairs

3. Date of Submission

July 16, 1998

4. Device Name

Classification Name:	Computed Imaging Device
Common/Usual Name:	Picture Archiving and Communications System (PACS)
Proprietary Name:	**Neo Imagery Technologies Inc.,** InSight™ Diagnostic Imaging Workstation

5. Substantial Equivalence

InSight™, Diagnostic Imaging Workstation, K965179;
AccuImage, AIDP (AccuImage Image Display Processor), K961023

6. Device Description and Intended Use

The InSight™ Diagnostic Imaging Workstation receives image files from medical scanning devices, such as CT or MRI and performs real-time viewing, image manipulation, three and four dimensional visualization, communication, and archiving. All of the functions are supported on standard personal computer platform for ease of cost and maintenance. The use of Microsoft Windows NT™ operating system makes the InSight™ Diagnostic Imaging Workstation easy to use and capable of being integrated with your other computer needs.

7. Software

Neo Imagery Technologies Inc. certifies that the InSight™ Diagnostic Imaging Workstation software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- identification of potential hazards, their causes, and their effects;
- development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

The hardware is "off-the-shelf" and complies with applicable electrical safety standards for standard PC hardware and peripherals.

10. Substantial Equivalence

The following product provides functions, which are substantially equivalent to this product:

Manufacturer:	**Neo Imagery Technologies**	**Neo Imagery Technologies**	**AccuImage**
Product Name:	InSight™	InSight™	AIDP
510(k) Number:	----------	K965179	K961023
Computer Platform:	Pentium/Windows NT	Pentium/Windows NT	Pentium/Win95
Image Format In:	Imatron Proprietary ACR NEMA 2.0 DICOM 3.0	Imatron Proprietary ACR NEMA 2.0 DICOM 3.0	Imatron Proprietary ACR NEMA 2.0 DICOM 3.0
Image Format Out:	DICOM 3.0 TIFF, BMP	DICOM 3.0 TIFF, BMP	BMP
Image Archive:	Magneto-Optical Drive, 2.6 GB	Magneto-Optical Drive, 2.6 GB	IDE Disk Drive, 1+G
Image Display:	Color/gray scale, CRT or Laptop PC LCD, up to 1024x1024, 12 bits	Color/gray scale, CRT or Laptop PC LCD, up to 1024x1024, 12 bits	Color/gray scale, CRT or Laptop PC LCD, up to 512x512, 12 bits
Image Processing:	Window-Level, Zoom, Variable smooth filter, Cine display	Window-Level, Zoom, Variable smooth filter, Cine display	Window level, Zoom, variable Filter: edge, sharpen, smooth Cine Display
Image Edit:	Manual Segmentation by drawing a contour. Segmentation by CT number threshold. (MIP, MinIP, radiographic projection), Surface rendering, Quick volume rendering, Volume rendering	Manual Segmentation by drawing a contour. Segmentation by CT number threshold (MIP), Surface rendering	Manual Segmentation by drawing a contour. Segmentation by CT number(MIP, MinIP), Surface rendered, Depth encoded surface, Quick Mip
Volume Rendering:	Maximum, or minimum Intensity Projection (MIP MinIP) Radiographic projection, Surface rendering, Quick volume rendering, Volume Rendering	Maximum Intensity Projection(MIP), surface rendering	Max or Min Intensity Projection (MIP, MinIP), Surface Rendered Depth encoded surface, Quick Mip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1998

Tina Young
CEO
Neo Imagery Technologies, Inc.
2315 South Birch Log Way
Hacienda Heights, CA 91745

Re: K982535
InSight™ Diagnostic Imaging Workstation
Dated: November 3, 1998
Received: November 4, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Young:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting 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): K982535

Device Name: Neo Imagery Technologies, Inc., InSight™ Diagnostic Imaging Workstation

Indications For Use:

The product is an image processing workstation software package designed to run on standard PC hardware. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user or supplied by NIT. The NIT InSight™ software receives image files from medical scanning devices, such as CT or MRI and performs real time viewing, image manipulation, 3D and 4D visualization, communication, and archiving.

(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 K982535

Prescription Use X OR Over-the-Counter Use____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)