

510(k) Summary of Safety and Effectiveness

2965179

JUL - 3 1997

1. Submitter's Information: Date prepared: November 5, 1996
Neo Imagery Technologies, Inc.
2315 South Birch Log Way
Hacienda Heights, CA 91745
(818) 333-3633
Fax (818) 961-0080
Contact Person: Ms. Tina Young

2. Proprietary Name: InSight™ Diagnostic Imaging Workstation
Common Name: Image Processing Workstation
Classification Name: RA 90 LLZ, Image Processing System, Class II
21 CFR § 892. classification unknown

3. Predicate Devices: Siemens V.I.P.™ , K893689
Virtual Imaging VIEW™ , K864854/A

4. Device Description:

The InSight™ Diagnostic Imaging Workstation provides real-time 3-D visualization, communication, archiving, characterization, and image enhancement with digital information received from medical scanning devices. System utilizes IBM compatible PC with Intel "X"86 family microprocessors and Microsoft Windows NT™ operating system for ease of maintenance and cost.

5. Intended Use of the Device:

The InSight™ system has the same intended use as the predicate devices. Namely, it is to aid the diagnosis of a trained medical practitioner in viewing images from CT, MRI and electronic images via image manipulation and data visualization.

6. Technological characteristics comparing to predicate devices:

The InSight™ system has no significant changes in technological characteristics from the predicate devices that will alter its safety or effectiveness. Similar to the predicate devices, the InSight™ system utilizes Intel microprocessors and Microsoft operating system to display images on a 21 inch monitor.

Special Controls: Although there are no performance standards established by the FDA on image processing workstations, Neo Imagery Technologies, Inc. has developed the InSight™ Diagnostic Imaging Workstation in compliance with the guidance issued by the FDA, CDRH, ODE such as the August 29, 1991 Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

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7. Substantial Equivalence:

The InSight™ Diagnostic Imaging Workstation has the same intended use and technological features as the predicate devices and does not raise new questions of safety and effectiveness. We believe the differences do not alter the intended diagnostic effect or affect its safety or effectiveness and therefore it is Substantially Equivalent to those predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tina Young
C.E.O.
NEO Imagery Technologies
2315 S. Birch Log Way
Hacienda Heights, CA 91745

JUL - 3 1997

Re: K965179
INSIGHT Diagnostic Imaging Workstation
Dated: April 18, 1997
Received: April 18, 1997
Unclassified/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 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

510(k) Number (if known) : _____

Device Name: InSight™ Diagnostic Imaging Workstation

Indication For Use:

The InSight™ Diagnostic Imaging Workstation must be used by or on the order of a physician. The system receives digital information from scanning devices and manipulates image data for the purpose of image characterization, enhancement, communication, archiving, and real-time 3D visualization. The system is designed as an aide to trained medical practitioners in the diagnostic process. Only qualified personnel should service system hardware and software.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (OR) Over-The-Counter Use _____

(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K9105179