

ScImage, Inc. NETRA™ Imaging Workstation 510(k) Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. **Submitter's Information:** Dated: March 4, 1996
 ScImage, Inc.
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- 2. **Common or Usual Name:** Medical Image Processing System
- Proprietary Name:** Netra™ Workstation System and Netra MD Software
- Product Classification:** 21 CFR § 892.1750, Product Code: RA 90 LLZ
 Image Processing System, Regulatory Class II

- 3. **Predicate Device:** SCRIBE™ Medical Image Processing System
 Multi-Dimensional Imaging, Inc., Newport Beach, CA
 FDA 510(k) Clearance Number: K 945428

4. **Description of Device:** The Netra™ Workstation System and NetraMD™ Software is a Medical Image Processing System and digital image communications system for use by the trained medical practitioner. The Netra™ Medical Image Processing System receives electronic information from medical imaging devices and manipulates that data for purposes of visualization, communication, archiving, characterization, comparison to other images and image enhancement.

It is similar in design to other such digital image communications system devices. It has microprocessor PC computer controlled solid state digital data and video receiving and transmission electronics and accessories.

5. **Statement of intended use:** The intended use is the same as the predicate device the MDI SCRIBE™ workstation. The Netra™ Workstation System and NetraMD™ Software is intended for viewing and manipulation of high quality MRI, CT, Ultrasound and X-ray electronic images as an aid in diagnosis for the trained medical practitioner.

The NetraMD™ Software system in conjunction with NETRA™ Imaging Workstation system is used for:

- 1.) receiving and storing of image data from a ACR/NEMA DICOM 3.0 compatible medical imaging scanning device, ACC/ACR/NEMA (DICOM 3.0) Digital Interchange Standard for Cardiology (DISC95-96) storage media, direct digital transfer from a medical imaging scanning device and video frame capture from a medical imaging scanning device.
- 2.) displaying and reviewing received images in individual image windows with window/level and panning/zooming controls, reformatting of 3D and 4D volumes in orthogonal and oblique planes, volumetric presentation of 3D and 4D volumes using 3D reconstruction and rendering, measurement of distances, areas and volumes, and manual segmentation of structures of interest for 3D presentation.
- 3.) sending image data to ACR/NEMA DICOM 3.0 compatible equipment, ACC/ACR/NEMA (DICOM 3.0) Digital Interchange Standard for Cardiology storage media, printer, scanning device monitor, independent monitor or other device for purpose of communication, archiving, review and display of medical diagnostic images.

The intended use is the same as the predicate device

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6. **Statement of technological characteristics:** The ScImage, Inc. NetraMD™ Software system in conjunction with NETRA™ Imaging Workstation system has no significant change in design, materials, energy source or other technological characteristics when compared to the predicate device. It has a microprocessor PC computer controlled solid state digital data and video receiving storage and transmission electronics and accessories. It is housed in a metal 7.5" wide by 22.5" deep by 20.5" high enclosure with formed thermoplastic front bezel. It's power source is selectable: 47/63 Hz, 90 to 264 VAC.

There are only minor configuration differences between the NetraMD™ Software and NETRA™ Imaging Workstation system and the MDI SCRIBE™ Workstation predicate device. These minor differences do not alter the intended use or affect the safety and effectiveness of the NetraMD™ Software and NETRA™ Imaging Workstation system when used as labeled.

The intended use and the technological characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to it.

Special Controls: Although there are no performance standards established by the FDA for these devices, the NetraMD™ Software and NETRA™ Imaging Workstation system has been designed, and manufactured to meet the following standards:

ACR/NEMA Digital Imaging and Communications in Medicine (DICOM) Standard, Version 3.0. A Conformance Statement is provided.

ACC/NEMA DICOM 3.0 Digital Interchange for Standard for Cardiology (DISC95-96)

The device and its development process also comply with the FDA, CDRH, ODE, August 29, 1991, Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

Performance tests were conducted by testing the system to the above standards and to the Netra™ design specifications. A DICOM 3.0 Conformance Statement is provided in the submission.

The performance evaluations indicated that the system met the standard's and requirements, consistently performed within its design parameters, and equivalently to the predicate device.

This data is summarized in the submission, and supports the safety and efficacy of the NetraMD™ Software and NETRA™ Imaging Workstation system.