

JUN 17 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Medical SNI Ltd. POB 25370 Haifa ISRAEL tel. +972.4.842.6192

Name of the Device: The Network System.

Description of the Device:

and Communication System (PACS). The system is intended to computerize Medical Image handling in Medical institutions. The computerization of the Medical records improves the efficiency of Medical Record handling and thus has a positive effect on Medical practice.

The Network System is intended to provide electronic management of the acquisition, storage, distribution and review of Medical Images.

Acquisition

the Network System from all medical modalities and digitized films.

Storage

archive is managed by a database.

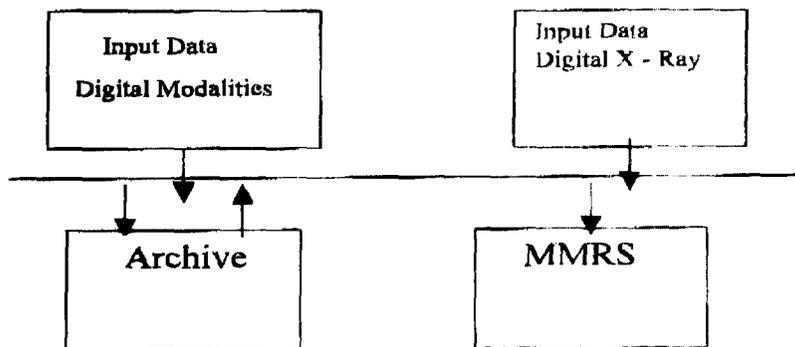
Distribution

and wide area networks based on standard TCP protocols.

Review

Reading Station (MMRS), the primary diagnostic reading station. The reading station has all necessary functions to enable full Radiological interpretation Images.

The Network System is shown schematically in the figure below:





JUN 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Eli M. Orbach, Ph.D.
International Regulatory Consultants
Medical SNI LTD
POB 6718, ERFRAT 90435 ISRAELRe: K980234
The Network System (Picture archiving and
communications system
Dated: May 28, 1998
Received: June 1, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Orbach:

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 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,

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) K980234

Device Name The Network System

Indications For Use:

The Network System is intended to provide electronic management of the acquisition, storage, distribution and review of Medical Images.

Management activities include:

Acquisition

the Network System from all medical modalities and digitized films.

Storage

archive is managed by a database.

Distribution

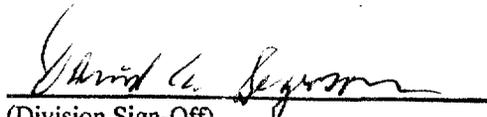
and wide area networks based on standard TCP protocols.

Review

Reading Station (MMRS), the primary diagnostic reading station. The reading station has all necessary functions to enable full Radiological interpretation Images.

(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 K980234

Prescription Use
(Per 21 CFR 801.109)

OR

Over The Counter Use

(Optional Format 1-2-96)