K980241

ATTACHMENT 5: 510(K) SUMMARY

MAR 17 1998

1. Submitter Information

NetCo Communications Corp.
NetCo Medical Data Management Division
6100 West 110th Street
Minneapolis, MN 55438

Contact: Tom Quintavalle, Manager of Quality Systems and Regulatory Affairs
Phone: 612-886-5403 tel
612-886-5474 fax

Summary Preparation Date: January 22, 1998

2. Device Names

Proprietary Name:	NetCo Medical Data Transportation Service software
Common/Usual Name:	medical image communications and storage device component
Classification Name:	No formal classifications have been issued for medical image management devices or their components
Classification:	Class I--proposed (See Federal Register Monday, December 2, 1996 Vol. 61, No. 232 p 63769 (Proposed rule) Docket No. 96-30650)

3. Predicate devices

- Sectra Imageserver 2000 Picture Archiving System [K963395]
- AGFA IMPAX 3000 [K934832]

4. Device Description

The DICOM storage service class functionality is provided by two applications that execute on the NAD platform. The applications act as proxies for DICOM storage Service Class Provider (SCP) devices and storage Service Class User (SCU) devices on either end of a transportation network connection. The storage SCP proxy is configure-able to emulate another SCP device that is the destination of DICOM data. The file is moved across the transportation network to one or more destination NADs. On the destination NAD is a proxy SCU application that is configured to emulate the original SCU that sent the data. The original DICOM message file is kept intact as it is processed through the originating NAD and transmitted via the pathway.

5. Intended use

The NetCo MDTS software is intended to be used in the transportation, storage, and retrieval of digital patient files.

6. Comparison of technological characteristics

The NetCo MDTS software and the predicate product software all employ proprietary software and DICOM file standards to interface with a health care subscriber's network to transmit, store and retrieve medical image data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1998

Tom Quintavalle
Manager of Quality Systems and Regulatory Affairs
NetCo.Communications Corp.
NetCo Medical Data Management Division
6100 West 110th Street
Minneapolis, MN 55438

Re: K980241
NetCo Medical Data Transporation
Service Software
Dated: January 22, 1998
Received: January 23, 1998
Regulatory class: Unclassified
Procode: 90 LMD

Dear Mr. Quintavalle:

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): K980241

Device Name: NETCO MEDICAL DATA TRANSPORTATION SERVICE SOFTWARE

Indications For Use:

The NetCo MDTS software is intended to be used in the transportation, storage, and retrieval of digital patient files.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Emil A. Leyva

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K980241

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)