

K961451

## 510(k) Summary

### Identification of the Product

JL - 3 1996

**Trade Name:** DicomNet  
**Common Name:** Unknown  
**Classification Name:** Angiographic X-Ray System (accessory)

**Manufacturer:** Lockheed Martin  
Communication Systems  
1 Federal Street (A&E 1C)  
Camden, NJ 08103  
(609) 338-3331  
(609) 338-2940 (fax)

**Contact Person:** Vincent J. Napoleon

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### Indications for Use:

DicomNet is intended to be used for storing and displaying digital images acquired and stored by digital imaging systems on DICOM interchange media. DicomNet reviews images directly from the DICOM storage media (CD-Recordable disks) and can store the images in an archive manager for review on any of the network review stations. The system stores unaltered/uncompressed computer digital data.

### Device Descriptions:

DicomNet is composed of the following:

**Cardiac Review Station:** A Power PC or Pentium based cpu review station capable of playback and annotation of images recalled from archival storage or read directly from MO disk.

**Archive Manager:** A workstation file server that provides management functions to the patient image database. The archive manager uses either the Metior HFM (Hierarchical File Manager) from Automated Network Technologies or the LSC HFM from Large Storage Configurations Inc.

**DLT Drive:** A high density, high speed, random access 1/2 inch tape archive providing real-time storage and retrieval of digital images.

**Automatic Tape Library:** A robotic tape library incorporating at least 1 but as many as 4 DLT drives that can be configured to store tens of thousands of patients on-line.

RAID: Redundant Array of Inexpensive Disks: Provides on-line storage of tens of patients, used for staging images from and to robotic tape library.

ATM Switch: (Asynchronous Transmission Mode) switch is a high performance network router that allows multimegabit per second transmission (point to point) from any peripheral in the network.

### **Marketing History**

In the opinion of Lockheed Martin, DicomNet is comparable and substantially equivalent to the following device:

<u>Model</u>	<u>Manufacturer</u>
GEMnet (K943355)	GE Medical Systems

The essential difference between DicomNet and GEMnet is DicomNet reads DICOM images from MO disks for network and archival while GEMnet formats directly from the digital acquisition system.

### **Potential Adverse Effects on Health**

The potential concerns are controlled by:

- Failure Mode and Effects Analysis (FMEA) to identify required controls
- Validation of the calculation models by phantoms
- Adherence to industry standards (UL)

### **Conclusions**

The principles of operation of DicomNet are almost identical to the currently marketed product GEMnet. this system poses no added risk of safety.