

K955708

Attachment J: Glossary

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510(K) SUMMARY

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### I. GENERAL INFORMATION

#### Establishment:

- Address: CompuMed Inc  
1200 No El Dorado Place C300  
Tucson AZ 85715
- Registration Number: 2029024
- Contact Person: Loren Larsen  
Manager, Regulatory Submissions  
520-544-0544 FAX 520-296-2555
- Date of Submission Preparation: December 5, 1995

#### Device Name:

- Trade Name: CompuMed DICOM Client
- Classification: No formal classifications have been issued and Communication Systems) or PACS components. For purposes of determining substantial equivalence, they have been considered to be accessories to medical imaging devices.
- Performance Standards: None established under Section 514 of the Food, Drug, and Cosmetic Act

### II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**

This premarket notification covers the LAN and WAN teleradiology concept (transmission), and study information distribution functions.

The CompuMed DICOM client is a viewing station manufactured by CompuMed, Inc. The CompuMed DICOM client is an on-site (LAN) or off-site (WAN or dial up) station for viewing patient information and images and reporting. It supports industry standard information transmission and communication protocols.

- **Technological Characteristics:**

The LAN and WAN (Teleradiology) products described are DICOM conformant. The CompuMed DICOM client is a low-cost viewing workstation for on-site and off-site viewing and reporting.

- **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use. It includes indications for use and cautions. This information provides for safe and effective use of the device.

- **Substantial Equivalence:**

The CompuMed DICOM client addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

- CompuMed PC Teleradiology product
- Dejarnette Teleshare
- Line Imaging WinRad
- SIENET DRC (MagicView workstation)

The CompuMed DICOM client products have the same intended use and similar technical characteristics as the devices listed above.

Phillip Bauer  
Signature

12/12/95  
Date