

# RADIOLOGY INFORMATION SYSTEMS

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## Appendix 5, Summary of Safety and Effectiveness Radiology Information Systems, Inc. RIS ScanView System (RSVS)

K970641

### 1.0 Submitted

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### 2.0 Product

Trade Name: Radiology Information Systems, Inc. RIS ScanView System (RSVS)  
Common Name: DICOM 3.0 compatible medical image display station  
Classification Name: Picture Archiving and Communication System (PACS).  
Proposed 892.2050 classifies PACS in Class II.

### 3.0 Predicate Device

The RSVS is substantially equivalent to the WinRad Teleradiology System (K936179) manufactured by Line Imaging Systems.

### 4.0 RIS ScanView System

The RIS ScanView System (RSVS) is a DICOM 3.0 compliant secondary capture image application. It can receive, store, transmit, and display images. It provides storage and query/retrieval service using C-STORE Service. The RSVS issues a DICOM 3.0 association request, RSVS starts sending the image data to the storage service provider. In addition, it can merge information from its keyboard with bitmap images from imaging devices to create DICOM 3.0 image files. The RSVS is a Microsoft Window based application.

### 5.0 RIS ScanView System Intended Use

The RSVS is intended for use as an image display and keyboard entry node on a DICOM 3.0 network. It's principal anticipated functions are to merge bitmap images from image sources with keyboard input patient

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information to form DICOM 3.0 patient image files and provide quality assurance review of such files.

## 6.0 Statement of Substantial Equivalence

The RSVS is substantially equivalent to the WinRad Teleradiology System (K936179) manufactured by Line Imaging Systems. The significant features of each device are compared below.

Function	RIS RSVS	WinRad
Input	Bitmap image	Bitmap image
Output	DICOM 3.0	DICOM 3.0
Store/Forward	yes	yes
Display Functions	yes	yes
Compression	no	yes

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