K962699

510(k) Summary

RADWORKS™ MEDICAL IMAGING SOFTWARE

Common/Classification Name: Digital Image Communications System

Applicare Medical Imaging B.V.
P.O.Box 416
2400 AK Alphen aan den Rijn
The Netherlands
Tel: (+31) 172 449 111
Fax: (+31) 172 449 129
E-mail: R.Kroon@applicare.nl

Contact: Ruud Kroon
Prepared: July 5, 1996

A.   LEGALLY MARKETED PREDICATE DEVICES

The **RadWorks™ Medical Imaging Software** is substantially equivalent to the ICON Teleradiology System by ICON Medical Systems (K911752), and the Images-on-Call Teleradiology System by Devices and Services Company (K896095).

B.   DEVICE DESCRIPTION

Section II of this submission contains a detailed description of the **RadWorks™ Medical Imaging Software**. The present section is intended as a summary. RadWorks™ is a stand-alone software product.

Introduction
The RadWorks™ medical imaging software consists of a basic module, RadWorks™ Review, and a number of optional modules, to enable the radiologist to view, retrieve, store, import process and transmit medical images. The RadWorks™ software is an open system which runs under the Microsoft® Windows NT™ operating system and it can operate on any hardware platform which meets the minimum hardware requirements and which supports the Windows NT™ operating system. Windows NT™ based workstations can be made part of UNIX, Novell NetWare, or other networks from major vendors. RadWorks™ is a stand-alone software product and involves no hardware except (optionally) a special graphics card. The minimum hardware configuration is discussed in Section II.

The basic component: RadWorks™ Review
RadWorks™ Review can display any digital monochrome image from CT, MRI, CR and US. Its built in colour option (using auto detect) also enables the display of 24-bit true colour images. This turns any RadWorks™ system into a true multi-modality workstation that can handle images not only from the Radiology department, but also from Endoscopy, Gastroscopy and other colour (video) sources.

000035

In monochrome mode, RadWorks™ Review offers features that are used routinely by radiologists and other medical specialists:
- Interactive windowing and an unlimited number of user definable pre-set window level buttons.
- Zooming up to 4 times using fixed settings or flexible zooming using a magnifying glass.
- A 'magic glass' with filtering and edge enhancement.
- A grey scale invert option.
- Interactive panning of zoomed images.
- Adjustable (multiple) cine loops for multiple image series.
- Annotation using markers and text.
- Measurement of pixel values, angles and distances.
- Histograms of pixel distribution along given lines and statistics of flexible regions of interest (ROIs).
- Fully configurable layout of viewports, toolbar positioning and a report option for text comments.

In colour mode, the images can be zoomed and panned.

Connections to the outside world
RadWorks™ can obtain data from various sources. Video images can be frame grabbed, using the Frame Grabber Module. Non DICOM 3.0 digital signals (ACR-NEMA 1.0 or 2.0 or proprietary) can be converted using Conversion Modules. Existing film and accompanying documents can be digitized and scanned using the Digitizer Module and the Document Scanning Module. Information from sources outside the hospital or from other departments can be received using (transparent) teleradiology over the hospital network, using conventional telephone lines, ISDN, T1 and ATM lines or satellite communications. In a departmental network or PACS any RadWorks™ station can open views on DICOM 3.0 compliant archives or other DICOM 3.0 compliant or RadWorks™ viewing stations and perform query and retrieve actions.

The other RadWorks™ modules
In addition to the basic viewing by RadWorks™ Review and the acquisition modules (Frame Grabbing, Digitizing/Document Scanning and Conversion), the RadWorks™ product line has many other modules available.

The Teleradiology Module provides high quality digital images in a well controlled and protected process. Teleradiology send and receive are taking place in the background, thus allowing for the continuation of viewing and reporting. Lossless compression is available, but also industry standard (DICOM) JPEG compression.

The MPR/MIP module offers high speed Multi Planar Reconstruction and Maximum Intensity͏ Projection.

The Study Compare option allows for opening various studies simultaneously for comparison.

The Print Module supports DICOM 3.0 printing, export to TIFF/BMP files and laser printing.

C.   INTENDED USE

The **RadWorks™ Medical Imaging Software** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices.

000036

D.   TECHNOLOGICAL CHARACTERISTICS

Both the **RadWorks™ Medical Imaging Software** and the ICON Teleradiology System are stand-alone software packages which can be used on more than one hardware platform. As long as minimum hardware requirements are met, the user is free to choose his/her own hardware platform.

All three systems can transmit to remote viewing stations over phone lines or networks. The RadWorks™ Lite remote software operates on a compatible PC in a receive only mode - it does not transmit. Two regular RadWorks™ systems can send and receive images to each other.

All three systems allow digital image processing and measurement capability. All three allow optional digitization of film images.

000037

E.   TESTING

The RadWorks™ Medical Imaging Software is tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part of Applicare's software development process as described in the Software Quality Handbook.

F.   CONCLUSIONS

The **RadWorks™ Medical Imaging Software** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices

The **RadWorks™ Medical Imaging Software** has the same technological characteristics as the predicate devices.

This premarket notification describes the characteristics of the **RadWorks™ Medical Imaging Software** in sufficient detail to assure substantial equivalence.

Applicare Medical Imaging B.V.