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Philips Medical Systems

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510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a 510(K) summary of safety and effectiveness for the following device.

CLASSIFICATION NAME: Automatic Radiographic Film Processor
(Class II, Tier 2, 21CFR 892.1900)

COMMON/USUAL NAME: Computed Radiography System

TRADE/PROPRIETARY NAME: Philips Computed Radiography (PCR) 5.2

ESTABLISHMENT NO.: 1217116

CONTACT PERSON: Peter Altman, Director of Regulatory Affairs

PERFORMANCE STANDARDS:

This device complies with the relevant national and international standards for electrical safety (UL-1950, IEC-601-1, and IEC-950) as well as the international standard for electromagnetic compatibility (IEC-601-1-2) and the ACR/NEMA DICOM Version 3.0 digital imaging communication standard.

SYSTEM DESCRIPTION:

A PCR system consists of an image reader, one or more PCR User Terminals, and an EasyVision PCR Printstation or optional EasyVision RAD workstation.

Imaging plates are exposed via conventional X-Ray devices. The imaging plates used in PCR systems are coated with a luminescent material which acts as an x-ray detector. It stores the x-ray image in the form of excited charge carriers. An exposed imaging plate is loaded into the image reader of the PCR system and the image stored on the imaging plate is scanned with a laser and converted to digital data. The digital X-ray image data is then routed to the EasyVision PCR Printstation or optional EasyVision RAD workstation for image processing, viewing, storing and/or printing to film if the workstations are connected to a compatible laser imager. The PCR User Terminal is used for the scheduling of patients and exams

The PCR User Terminal consists of a Pentium-based PC, a keyboard, an operator terminal with function keys, and an optional bar-code reader. PCR User Terminals may be interconnected via standard ethernet.

Three image reader types, currently AC2, AC3 and 9000, can be connected to the system in order to meet different requirements based on image plate size and throughput.. The image readers are manufactured by Fuji Photo Film Co. Ltd. **The AC2 has been granted a 510(k) clearance. Refer to accession number K896050A. The AC3 has been granted a 510(k) clearance. Refer to accession number K944046. The 9000 has been granted a 510(k) clearance. Refer to accession number K951373.**

SYSTEM DESCRIPTION: (cont'd)

The EasyVision PCR Printstation is a workstation that provides image storage, display, printing and processing functions using a SUN computer. The optional EasyVision RAD workstation is also a SUN computer that provides the same functions as the Printstation but it also provides more storage capability and additional post-processing functions. Both workstations are able to export digital images to the network via the DICOM protocol. **These workstations have been granted a 510(k) clearance. Refer to accession number K953095.** Digital image data from the image readers are processed based on selection of either an UnSharp Masking (UM) algorithm or a Dynamic Range Reconstruction (DRR) algorithm. The DRR algorithm is a processing feature of the PCR 5.2 system not previously available on other computed radiography systems such as the predicate device PCR ACe which uses an Unsharp Masking algorithm. The DRR algorithm provides higher transparency in radiological dense areas. The result is a display which shows more information and thus avoids alterations to the presentation parameters which would otherwise be necessary. Processing with DRR improves low contrast resolution.

PCR 5.2 System functions are listed in the table below

Function	Description
Demographic Data Entry	For each image, demographic data identifying the patient and describing the examination are entered.
Image Plate Reading	An image stored on a stimulated phosphor image plate is read and digitized.
Demographic Data Linking	Linking of demographic data to the appropriate image plate.
Image Processing	Spatial enhancement and contrast enhancement algorithms are applied to digitized raw images.
Viewing	Images may be viewed on a monitor in order to check for appropriate positioning and other examination details.
Printing	Images may be routed to a laser hardcopy unit.
Export	Images may be exported to other digital imaging systems, such as viewing stations or archives.
Storage	Images may be stored locally on optical disk.

INTENDED USE:

The PCR 5.2 System is a digital film processing system for reading and then digitizing X-ray images from reusable imaging plates which have been exposed in conventional radiographic examination devices. The digitized X-ray images can then be viewed, stored, post-processed and printed. The Philips PCR system can be used in all conventional RAD/RF examination situations, except for mammography. PCR is suitable for routine RAD exams as well as specialist areas, like intensive care units, trauma departments and pediatric departments.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The Philips PCR 5.2 system is a modification of, and considered substantially equivalent to the Philips PCR ACe system manufactured by Philips Medical Systems based on a comparison of the technological characteristics of the PCR 5.2 system to those of the PCR ACe system. **The PCR ACe system has been granted a 510(k) clearance. Refer to accession number K915237.** Also, the image processing algorithm called Dynamic Range Reconstruction (DRR) used with PCR 5.2 is considered substantially equivalent to the Unsharp Mask (UM) algorithm implemented by Fuji and used with the image reader for the PCR ACe system and it is also substantially equivalent to the Dynamic Range Control (DRC) algorithm also implemented by Fuji and used on the 9000 image reader. The DRC algorithm has been granted a 510(k) clearance as part of the 9000 image reader. Refer to accession number K951373.