Camtronics
MEDICAL SYSTEMS

K954159

510(k) Summary

MAR 19 1996

Date prepared: August 28, 1995
Name of contact person: Robert Kriedermann
Device trade name: Digital Imaging System
Common name: Digital Imaging System
Classification name: Medical Image Picture Archiving and Communications Device
Predicate substantially equivalent devices: Camtronics Ltd. Video Plus (K941979), Siemens Medical Systems Fluorospot H version 2 (K914525)
Device description: Digital image recording and display system fo use in a cardiac catheterization laboratory or radiography/fluoroscopy suite.
Intended use:

- Image Acquisition
- Display Control/Image Processing
- Input /Output Control
- Patient Data Management

Predicate device specifications comparison:

	Principal Device	*Predicate Device*	*Predicate Device*
Feature	**Camtronics Digital Imaging System**	**Camtronics Video Plus (K941979)**	**Siemens Fluorospot H version 2 (K914525)**
Matrix size	512^2 to 2068^2	512^2 to 1024^2	1024^2
Max. acquisition rate	60 fps	60 fps	8 fps
Bit depth	8, 10, or 12	8	8
Image storage	1 gigabyte minimum	1 gigabyte minimum	650 megabyte
Networking	yes	yes	yes
Supported procedures			
Fluoro Acquisition	yes	yes	yes
Fluoro Loop Record	yes	yes	yes
Roadmapping Fluoro Acquisition	yes	yes	yes
Spot Film Verification	yes	yes	yes
Digital Spot Acquisition	yes	yes	yes
Digital Subtraction Angiography Acquisition (DSA)	yes	yes	yes
Peripheral Angiography Acquisition (PERI)	yes	no	yes
Digital Tomography Acquisition (TOMO)	yes	no	yes
Rotational Angiography Acquisition	yes	no	yes
ECG Gated Acquisition	yes	no	no
ECG Trace(s) Display	yes	no	no
Cine	yes	yes	no
Filmless Cine	yes	yes	no
Electrophysiology (EP)	yes	no	no
Synchronized Biplane Acquisition	yes	yes	no

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Predicate device specifications comparison (continued):

	Principal Device	*Predicate Device*	*Predicate Device*
Feature	**Camtronics Digital Imaging System**	**Camtronics Video Plus (K941979)**	**Siemens Fluorospot H version 2 (K914525)**
Window/level	yes	yes	yes
Edge enhancement	yes	yes	yes
Zoom	yes	yes	yes
Roam	yes	yes	yes
Roadmapping	yes	yes	yes
Peak opacification	yes	yes	yes
Remask	yes	yes	yes
Pixel shift	yes	yes	yes
Annotation	yes	yes	no
Qualitative analysis	yes	yes	no

Compression ?

Performance data: Not required for determination of substantial equivalence for this class of device.

Conclusions drawn from clinical and nonclinical test data: Not required for determination of substantial equivalence for this class of device.