3/17/99

Camtronics
MEDICAL SYSTEMS

510(k) Summary

K990066

Date prepared: January 4, 1999
Name of contact person: Robert Kriedermann
Device trade name: CCD Camera
Common name: CCD Video Camera
Classification name: System, X-ray, Fluoroscopic, Image-intensified
Predicate substantially equivalent devices: K953974 MediVision-Medical Imaging Ltd. "Camvision 1000"

Device description and intended use: This device is a Charge Coupled Device (CCD) video camera for use in digital radiography, including DSA, high resolution cardiology, and low dose fluoroscopy. It is designed for use with X-ray image intensifiers in diagnostic imaging chains.

Predicate device specifications comparison:

	Principal Device	***Predicate Device***
	Camtronics CCD Camera	**K953974 MediVision-Medical Imaging Ltd. "Camvision 1000"**
CCD and analog circuitry		
CCD type	interline	interline
Scanning	progressive	progressive
Resolution	1024 x 1024	1024 x 1024
Contrast resolution	12 bit, 4096 gray levels	10 bit, 1024 gray levels
Anti-blooming	automatic control, up to 100:1	automatic control, up to 100:1
TV parameters		
Video output	High-line interlaced, 1.0 V peak to peak on 75 ohm	composite video RS-343A or progressive scan, 50 or 60 Hz, 1.0 V peak-to-peak on 75 ohm
Digital output	RS 644	RS-422 AIA compatible
Bandwidth	12 bit 40 MHz	input equivalent to 20 MHz, output equivalent to 40 MHz
Dynamic range	66 dB	60 dB
Signal to noise ratio	greater than 1000:1	1000:1 at camera's connector
Gamma	adjustable or linear	adjustable, 0.45-1.0
Frame rate	up to 25 or 30 frames per second	up to 25 or 30 frames per second
Fast frame rate	50 or 60 frames per second at 1024 x 512. 30 fps at 1024 x 1024	50 or 60 frames per second at 1024 x 512
X-ray and image control		
Internal controls	automatic gain control (AGC) automatic anti-blooming level (AAL)	automatic gain control (AGC) automatic anti-blooming level (AAL) automatic integration control (AIC)
External controls	video gain select horizontal scan reverse vertical scan reverse black level select	video gain select anti-blooming level select horizontal scan reverse vertical scan reverse black level select
Video synchronization	internal or external	internal or external
Fluoroscopy control	automatic brightness control (ABC)	automatic brightness control (ABC)
Iris control	motorized control	automatic control

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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.

Substantial equivalence summary: The Camtronics CCD Camera is a comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the CCD Camera is the same as that of the predicate device "Camvision 1000", marketed by MediVision-Medical Imaging Ltd. No new safety or effectiveness issues are raised with the Camtronics CCD Camera. The subject device has substantially equivalent technological characteristics, features, specifications, materials, modes of operation, and intended uses as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

Robert Kriedermann
Regulatory Specialist
Camtronics, Ltd.
900 Walnut Ridge Dr.
Hartland, WI 53029

Re: K990066
CCD Camera, Model 9000
Dated: January 4, 1999
Received: January 8, 1999
Regulatory class: II
21 CFR 892.2030/Procode: 90 LMA

Dear Mr. Kriedermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K990066

DEVICE NAME: Camtronics CCD Camera

INDICATIONS FOR USE:

This device is a Charge Coupled Device (CCD) video camera for use in digital radiography, including DSA, high resolution cardiology, and low dose fluoroscopy. It is designed for use with X-ray image intensifiers in diagnostic imaging chains.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990066