Camtronics
MEDICAL SYSTEMS

K992666

OCT 13 1999

510(k) Summary

Date prepared: August 2, 1999
Name of contact person: Robert Kriedermann
Device trade name: Video Plus software upgrade
Common name: Digital Image Acquisition Unit
Classification name: Picture Archiving and Communications System

Predicate substantially equivalent device: GE Medical Systems "Advantx DLX" K945459, K926258

Device description and intended use: This is a software upgrade for the existing Video Plus System cleared under K954159. This release encompasses some general enhancements and more integrated support for certain vendors.

Predicate device specifications comparison:

	Principal Device Camtronics Video Plus	***Predicate Device*** GE Medical Systems "Advantx DLX" K945459, K926258
Digital video input	yes	no
Linked Biplane acquisition	yes	yes
Auto injection	yes	yes
Histogram equalization	yes	yes

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 Video Plus is a comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the Video Plus is the same as that of the predicate device "Advantx DLX", marketed by General Electric Medical Systems. No new safety or effectiveness issues are raised with the Camtronics Video Plus. 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

OCT 13 1999

Robert Kriedermann
Regulatory Specialist
Camtronics, Ltd.
Medical Systems
900 Walnut Ridge Drive
Hartland, WI 53029

Re: K992666
Video Plus System Series 95000
Dated: August 2, 1999
Received: August 9, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Kriederman:

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): K992666

Device Name: Video Plus

Indications For Use:

Video Plus is a digital imaging acquisition and review system for the cardiac catheterization lab. Its features include digital fluoroscopy, digital cine, real time processing during acquisition, DSA processing, image processing, quantitative coronary analysis, digital subtraction angiography, digital video input, linked biplane acquisition, auto injection, and histogram equalization.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992666

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)