



APR 15 1999

510(k) SUMMARY

K 990759

1 DATE PREPARED

March 2, 1999

2 CONTACT PERSON

Pascal M. Kaufmann
Quality Assurance Director

3 DEVICE NAME

Proprietary Name: **VIEW COM**
Common Name: Image Digitizer and Communication System;
Radiology Panel; 90LLZ - System, Image Processing
Classification Name: Picture Archiving and Communications Systems (PACS)
21CFR892.2050
(Federal Register / Vol. 63, No. 82 / April 29, 1998)

4 DEVICE DESCRIPTION AND INTENDED USE

The VIEW COM is a Software Device intended to digitized and to communicate Cardiac and Cardiovascular Images from the Procedure Room to Local Network in DICOM Format.

Such Digitized Images will be visualized and archived by independent DICOM entities.

5 SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE(S)

Substantial Equivalence Comparison

Specifications	VIEW COM (This 510(k))	View Archiving Station (VAS)	Video Plus with Analytical Workstation
Manufacturer	Electromed	Electromed	Camtronics
510(k) Number	---	K971176	K941979
Classification	892.2050; Class II	892.1600; Class II	892.1600; Class II
Operating System	Windows NT	Windows 3.11	Unknow, not essential for Substantial Equivalence
Archiving	<ul style="list-style-type: none"> • Hard Disk • SCP DICOM; External on other DICOM Entity • CD-R; External on other DICOM Entities 	CRV; Internal	<ul style="list-style-type: none"> • Hard disk • CD-R
Video:			
- Analogic Input	525, 625, 1023, 1049, 1249; interlaced or progressive	525, 625, 1023, 1049, 1249; interlaced or progressive	525, 625, 1023, 1049, 1249; interlaced or progressive
- Display	No diagnosis, display only	Diagnosis	Diagnosis
- Image Compression	JPEG - Lossless JPEG - Lossy	JPEG - Lossless JPEG - Lossy	JPEG - Lossless JPEG - Lossy
- Image Processing	No	Yes	Yes
- Frame rate	≤30 fps	25 or 30 fps	≤60 fps
Acquisition:			
- Input Acquisition	Video	Video	Video
- Stored Image Matrix	512 x 512	512 x 512	512 x 512 or higher
- Gray Scale Resolution	8 bits, 256 levels	8 bits, 256 levels	8 bits, 256 levels
- Output	DICOM	DICOM	DICOM
Communication:			
- Networking	Yes	Yes	Yes
- Transfer Mode	TCP/IP	TCP/IP	TCP/IP
- Exchange Format	DICOM	DICOM	DICOM

6 SAFETY AND EFFECTIVENESS STATEMENT

The intended use and technological characteristic of the VIEW COM Software Device are similar or equivalent to the Predicate Device(s). Any differences between the VIEW COM Software Device and the Predicate Device(s) have no significant influence on the safety and/or effectiveness of the Device

7 CLINICAL PERFORMANCE DATA

Not required for determination of substantial equivalence for this class of device.

8 CONCLUSION DRAWN FROM CLINICAL AND NONCLINICAL TEST DATA

Not required for determination of substantial equivalence for this class of device.



APR 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pascal M. Kaufmann
Quality Assurance Director
Electromed International
310 Boul Industriel
St-Eustace, Quebec
Canada J7R 5R4

Re: K990759
View COM, Digitizer and
Communications Device
Dated: March 4, 1999
Received: March 8, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Kaufmann:

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



ELECTROMED INTERNATIONAL

Electromed International
310 Boul. Industriel,
St-Eustace, Québec, Canada,
J7R 5R4
Tél.: (450) 491-2100
Fax: (450) 491-4138

Indication for Use Statement

510(k) Number (if known):

K 990 759

Device Name:

VIEW COM

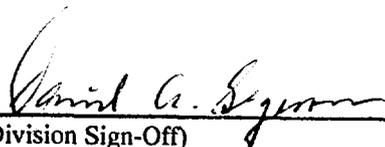
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K990759

Prescription
Use

X

OR

Over-the-Counter
Use

(per 21CFR801.109)