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Certified ISO 9001 Certified

K971176

Sept. 3, 1997

510(k) NOTIFICATION (VIEW ARCHIVING STATION)

APPENDIX B **(510(k) SUMMARY)**

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February 17, 1997

SUBMITTER: Electromed International
310 Industrial Blvd.
St. Eustache, Quebec
Canada J7R 5R4
Tel.: (514)-491-2100
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PREPARED BY: James Riedl

CLASSIFICATION NAME: Picture Archiving and Communication System, CFR 892.2050 (CLASS II)

COMMON OR USUAL NAME: Vascular image archiving, and communications station

PROPRIETARY NAME: VIEW ARCHIVING STATION
(Vascular Integrated Electromed Workstation)

PREVIOUSLY MARKETED DEVICE TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED: Sony Medical System's "Cinenet Cardiac Image Network" (K924708) and Diagnostic Archive's "Cardiac Image Management System (CIMS)" (K925961)

The VIEW Archiving Station represents the first generation of Electromed International's vascular image archiving and communication stations. The VIEW Archiving Station is intended for vascular image archiving, processing, analysis, management, and communication as the Cinenet Cardiac Image Network with the exception of analysis which is available as an option with the Cardiac Image Management System (CIMS). Some of the features offered in the VIEW Archiving Station are: vascular image archiving, image processing (zoom, panning, edge enhancement, contrast), analysis (left and right ventricular functions, quantitative coronary analysis), and communication (printing of reports and sending of exam information in DICOM or Electromed encapsulation over a local area network, including images). Images are acquired in real-time on both products.

The VIEW Archiving Station may be interfaced directly with the majority of image digitizers available in todays angiographic systems. It may be linked to video signals of 1249 lines at 25 images/sec or even 1049 lines at 30 images/sec. The video signal is then re-sampled in real time to yield a signal of 625 lines which then may be recorded on a laser video disc by the CRV.

The View Archiving Station is comprised of two principle assemblies: the Electronic Cabinet; and the User Console which is connected solely to the Electronic Cabinet. Unlike the Cinenet Cardiac Image Network which uses digital videocassettes as the archiving media, the VIEW Archiving Station archives it's images on laser video discs and the exam information on internal hard disks. Each uniquely numbered laser video disc holds

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approximately 48 minutes (24 per side) of recording time, 35-45 examinations. The internal hard disks encompasses records that contain patient and exam information along with the referenced video laser disk ID number, which in turn, contains the recorded images. Approximately 100,000 records can be maintained on the internal hard disks at the present time. The Cinenet Cardiac Image Network incorporates a Data Storage Library which contains anywhere from 84 to 1008 digital video cassettes for automatic retrieval, whereas the VIEW Archiving Station acts as a stand alone unit whereby the laser video discs are manually inserted when prompted.

The VIEW Archiving Station is to be connected to a 230V (±10%), 50/60Hz, 10A power source.

The configurable and add-on options being offered with the VIEW Archiving Station are: Room Loop Playback (the viewing of images on a remote monitor in the procedure room); Table Side Joystick (remote console in the procedure room to control the playback of recorded images); SVHS Copier (the recording of exams onto a SVHS tape); and a High Definition Printer Station (printing of reports, including reference images at 1200dpi and 256 gray scale levels, via an ethernet local area network).

Since the VIEW Archiving Station can transmit information and images in a Dicom compliant format, via an ethernet local area network, a CD-R Station may be connected to the network to record exams onto a transportable media (CD). The CD-R Station is not part of this 510(k) submission.

Since the options or combination of options, as stated above, are available as an integral part of the VIEW Archiving Station, the device will inevitably be offered in various configurations while maintaining the intended use and technological characteristics presented here within.

The VIEW Archiving Station does not in any way raise new questions of safety or effectiveness, when used as labeled, in comparison to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 1997

James Riedl
Quality Director
Electromed International
310 boul. Industriel
St-Eustache (Quebec)
Canada J7R 5R4

Re: K971176
View Archiving Station (Vascular Image Archiving and Communication Station)
Dated: July 7, 1997
Received: July 9, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Riedl:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX C (INTENDED USE)

Device:	*Picture archiving and communications system, 21 CFR 892.2050, (CLASS II)*
Model:	*VIEW ARCHIVING STATION*
Intended Use:	*Vascular image archiving, processing, analysis, management and communication.*

Note: *For further details, please refer to the VIEW ARCHIVING STATION User Manual*