ELECTROMED INTERNATIONAL
310, boul. Industriel, St-Eustache (Quebec) Canada J7R 5R4
Tel.: (514) 491-2100 Fax: (514) 491-4138

Certifié ISO 9001 Certified

K974255

JAN 27 1998

APPENDIX C (510(k) SUMMARY)

510(k) SUMMARY

SUBMITTER: Electromed International
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St. Eustache, Quebec
Canada J7R 5R4
Tel.: (514)-491-2100
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October 24, 1997

PREPARED BY: James Riedl

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

COMMON OR USUAL NAME: CD writer and CD reader stations of digital cardiac images

PROPRIETARY NAME: CD-R STATION & VRS-2000

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 CD-R STATION & VRS-2000 represents the first generation of Electromed International's CD writer and CD reader stations of digital cardiac images, Componets of "Picture Archiving and Communication System, CFR 892.2050 (CLASS II)". The Cinenet Cardiac Image Network, and the Cardiac Image Management System are complete systems which comprise of the following functions: image archiving; processing; analysis, management; and analysis. The CD-R STATION & VRS-2000 is intended solely for the engraving of DICOM compliant images from a local area network onto a CD, and for the viewing of the recorded images on the CD.

The CD-R STATION & VRS-2000 is comprised of two principle assemblies: a personal computer and a monitor. Unlike the Cinenet Cardiac Image Network which uses digital videocassettes as the archiving media, the CD-R STATION & VRS-2000 does not archive at all. The CD-R STATION is to be interfaced to a local area network to receive DICOM compliant images which may then be recorded onto a CD. The VRS-2000 is a stand alone station which reads DICOM compliant images from a CD and displays them on a computer monitor. The media (CD) is not to be used as an archiving media, but rather only as a transportable media to review images and reports. The internal hard disks of the CD-R STATION & VRS-2000 are used only for running the software and to temporarily buffer the images / reports which are to and from the CD. Only the images of a single patient can be transferred to a single CD, whereas the Cinenet Cardiac Image Network incorporates a Data Storage Library for archival which contains anywhere from 84 to 1008 digital video cassettes for automatic retrieval.

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The CD-R STATION & VRS-2000 is to be connected to a 115/230V (±10%), 50/60H_Z, 2.6/1.3A power source.

The configurable and add-on options being offered with the CD-R STATION & VRS-2000 is a CD label printer and a optional mobile cart.

Since the CD-R STATION & VRS-2000 can receive information and images in a DICOM compliant format, via a local area network, a CD-R Station may be connected to a VIEW ARCHIVING STATION (510k #K971176) to record the previously archived images onto a transportable media (CD).

Since the options or combination of options, as stated above, are available as an integral part of the CD-R STATION & VRS-2000, the device will inevitably be offered in various configurations while maintaining the intended use and technological characteristics presented here within.

The CD-R STATION & VRS-2000 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

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

Re: K974255
CD-R Station and VRS-2000
Dated: November 3, 1997
Received: November 13, 1997
Regulatory class: Unclassified
Procode: 90 LMD

JAN 27 1998

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

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

510(k) Number (if known): K975255

Device Name: CD-R Station and VRS-2000

Indications For Use:

CD writer (CD-R STATION) is intended solely for the engraving of DICOM compliant images from a local area network and the CD reader (VRS-2000) is used for viewing the images either from the CD or directly from a local area network.

The media (CD) is not to be used as an archiving media, but rather only as a transportable media to review images and reports. The internal hard disks of the CD-R Station and VRS-2000 are used only for running the software and to temporarily buffer the images / reports to and from the CD and local area network.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David L. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K975255

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