

AUG 20 1998

SHL
TeleMedicine
International Ltd.

K981807

510(k) Summary of Safety and Effectiveness

Submitter Information: SHL Telemedicine International Ltd.
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FDA/CDRH/ODE/DMC

Proprietary Name and Model: Cardio Vision Software

Common/Usual Name: ECG Display and Storage Software

Classification Name: Electrocardiograph (21 CFR 870.2340)

Predicate Device: The predicate devices are the Micromedical Cardioview Transtelephonic Software (k955891) and the Instromedix Cardiomagix Software (k925639).

Device Description:

The Cardio Vision software is a program which runs on a personal computer and is used for the display and storage of Electrocardiogram recordings. The software receives an input signal containing the ECG data from an ECG receiving center. The receiving center is connected to the computer on which the Cardio Vision software is running via a serial port. The ECG receiving center receives the ECG signal from an ECG recording device either via direct connection or via telephone. The software interprets the digital signal and displays it on the screen in real time as a single or multiple lead ECG plot.

The received ECG signal can be stored on the disk and can be compared to previous ECG recordings for that patient. In addition, measurements can be performed on the ECG plot.

Intended Use:

The Cardio Vision software is intended for use by trained medical staff for visualization and measurement of ECG recordings to be used in the monitoring of a patient's cardiac condition together with knowledge of the patient's general condition and other medical data on record.

Comparison to Predicate Device:

The Cardio Vision Software has the same intended use, basic features, and target population as its predicate devices. The Cardio Vision Software and its predicate devices all display, store, and enable convenient analysis of





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ECG signals received via a serial port from a locally or transtelephonically connected ECG receiving center.

Safety:

The risk of all identified potential safety hazards is reduced by software design and testing and by the use of the device only by trained medical staff.

Bench Data:

An artificial signal was fed into the receiving center, and the resulting ECG data was displayed and written to a log file. Comparison of the log file with the original signal verified that the data sampling and data processing modules function properly.

Using the ECG display module to display data from prepared files verified that the data was displayed properly and in the correct scale.

Clinical Data:

The comparison of Cardio Vision Software printouts with simultaneous ECG strip chart output demonstrated that the Cardio Vision Software processes and presents ECG data consistently and accurately.

Substantial Equivalence:

The safety and effectiveness of the Cardio Vision software are similar to that of its predicate devices. It is SHL's opinion that the Cardio Vision software is substantially equivalent to its legally marketed predicate devices in terms of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1998

Mr. Alroy Yariv
Vice President
SHL Telemedicine International, Ltd.
90 Yigal Alon Street
TEL AVIV,
ISRAEL

Re: K981807
CardioVision Software Model S-CV5096
Regulatory Class: II (Two)
Product Code: DPS
Dated: May 21, 1998
Received: May 21, 1998

Dear Mr. Yariv

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.

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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) 594-4648. 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" (21CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 981807

Device Name: CARDIO VISION SOFTWARE

Indications For Use:

VISUALIZATION AND MEASUREMENT OF ECG
RECORDINGS TO BE USED BY TRAINED MEDICAL
STAFF IN THE MONITORING OF CARDIAC CONDITION.

(Please do not write below this line-continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation(ODE))

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____