K012349

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510(k) Summary

MetaVision 5.0
Clinical Information System

Common/Classification Name: Medical Cathode Ray Tube Display,
21 CFR 870.2450

*i*MD*soft*, Ltd.
Kiryat Atidum, Building 4
Dvora Hanevi's Street
Tel Aviv 61581
ISRAEL

Contact: Yoav Palit
Prepared: June 27, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

MetaVision is substantially equivalent to the Hewlett-Packard Carevue 9000 Clinical Information System that was cleared for marketing as K992636 on August 31, 1999.

B. DEVICE DESCRIPTION

The **MetaVision** Graphical ICU Patient Information System is a clinical information system utilized for data collection, display, management, and storage in the ICU environment. The ICU may be a normal adult ICU, a neonatal ICU, or other type of ICU. The system can communicate with bedside devices that are attached to a local network. The system may display patient data on one or more work stations running under the Windows NT/2000 operating system.

The **MetaVision** system is resident on a server and one or more workstations and communicates via a network with other workstations and patient monitoring devices on the network. The **MetaVision** system can also communicate with a number of remotely located patient care units.

C. INTENDED USE

The MetaVision Graphical Patient Information System is indicated for use in data collection, display, management, and storage in the intensive care unit.

The system is used in conjunction with independent patient bedside devices and systems, connected via a network.

The way the system is used for generating patient records, computation of drug and fluid dosage and research tasks is determined by the health care providers, in terms of their environment and requirements.

The MetaVision application is resident on a workstation that provides for data input and patient data display--to health care professionals.

Typically, a MetaVision system comprises several workstations connected via a network system to one or more servers. Data is stored and managed by servers.

The MetaVision system network can communicate with a number of remotely located patient care units.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **MetaVision** is a medical device, and it has very similar indications for use as the legally marketed predicate device, and it has the same intended use--the display of patient medical information. The **MetaVision** has the same technological characteristics as the predicate device--both are software products operating in a network environment. This premarket notification will describe the characteristics of the **MetaVision** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are identical to those of the predicate device. Both employ software and computers to communicate with patient monitoring devices and other workstations to enter and display patient data.

F. TESTING

Software is tested according to well-controlled procedures at *i*MD*soft*.

G. CONCLUSIONS

The 510(k) has demonstrated Substantial Equivalence with the predicate device. The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Mr. T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates
12300 Twinbrook Parkway
Suite 625
Rockville, MD 20852

Re: K012349
Trade Name: MetaVision Graphical Patient Information System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: November 13, 2001
Received: November 15, 2001

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

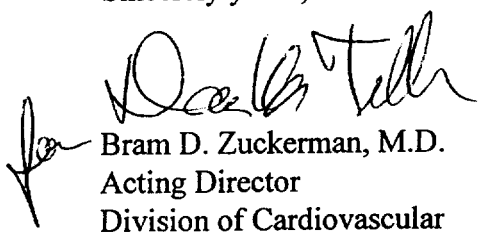
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MetaVision Graphical Patient Information System

Indications For Use:

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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 of Cardiovascular & Respiratory Devices
510(k) Number K012349

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