DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1997

Kontron Instruments, Ltd.
c/o Mr. Randall C. Mathieson
CPC Corporation
200 Cascade Boulevard
Milford, Connecticut 06460

Re: K971038
Kontron Kolormon Plus ECG with Respiration Module 7271-500 only
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: August 4, 1997
Received: August 6, 1997

Dear Mr. Mathieson:

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 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) 594-4648. 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" (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,

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): K971038

Device Name : KOLORMON *plus* ECG WITH RESPIRATION MODULE 7271-500

Indications for Use:

The 7271-500 module monitors ECG and Respiration, and the results are displayed on a Kolormon host system.

The ECG and respiration are measured from a 3 lead system providing an ECG waveform and heart rate from one of three selectable ECG vectors as well as a respiration waveform and respiration rate. Respiration is also measured from the active ECG electrode pair. There are two AC coupled sources of power to the front end to power the ECG and respiration circuits. Current is injected into the patient through the ECG electrodes to detect when a lead falls off the patient and through the respiration electrodes to determine the thoracic impedance across the chest to which the respiration cycle correlates. Measurement of the ECG waveform is by potential difference between two of three possible electrodes. The electrode pair is user selected.

The module may be used on either adults or neonates by selecting the adult/neonate option link in the module.

The Kolormon system is a generic patient monitor used in the operating theatre, critical care unit or as a bedside monitor on the ward. Its purpose is to measure and display clinical parameters of a patient via the module and module housing.

The basic system comprises a host monitor and its module housing. Modules, capable of measuring one or more clinical parameters of a patient to which they are connected, may be inserted into the module housing from which the clinical parameters for that module will be monitored. The generic nature of the system comes from the ability to select clinical parameters for monitoring by insertion of the appropriate modules.

The host has a colour screen which displays up to 6 waveforms, numeric values of the clinical parameters monitored (termed derived parameters), trends of clinical parameters, messages (information/cautions and warnings) and labels for keys used to select functions of the modules. There are a set of keys which control the basic functions of the monitor and a strip of six trikeys used to select module functions. Sets of key labels are presented at the bottom of the screen defined by the module whose keys have been selected for display and the previous key selections for that module.

Concurrrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971038