DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1998

Mr. Joel Orlinsky
Medical Research Laboratories, Inc.
1000 Asbury Drive
Buffalo Grove, IL 60089

Re: K983307
Portable Intensive Care Unit (PIC)
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: October 26, 1998
Received: October 29, 1998

Dear Mr. Orlinsky:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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 not 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/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

Enclosures

.510(k) Number (if Known):_____

Device Name: PIC (with SAED option)

Indications For Use:
Without the SAED option, the PIC is intended primarily for use by emergency responders, trained in advanced life support, cardiac care techniques, interpretation of ECG waveforms, and the use of the PIC. With the SAED option, the PIC may be used by emergency responders, trained in basic life support, cardiac care techniques, and the use of the PIC. The usage may be in an ambulance or at the scene of an emergency. The PIC is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. It is also intended to be used during the transport of patients between any of the locations mentioned above. The patient population will consist of adults and children (described below), and will consist of patients both with and without heart dysfunction. The PIC will be used primarily on patients experiencing symptoms of cardiac arrest or in a post trauma situation. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device. Indications for each of the specific functions are discussed below:

DEFIBRILLATOR FUNCTION:
The defibrillator function of the PIC is used to treat: ventricular fibrillation and pulseless ventricular tachycardia. In the manual mode, patients may range from neo-natal to adult. The semi-automatic mode should not be used on small (less than 8 years old) pediatric patients.

DEFIBRILLATOR (INTERNAL PADDLE) FUNCTION:
With internal paddles, the defibrillator function of the PIC is used for the termination of ventricular fibrillation during cardiac surgery, with the paddles applied directly to the

Continued on Page 2

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

Concurrence of CDRH, Office of Device Evaluation (ODR)

Mark Kramer

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

heart. Patients may range from neo-natal to adult

ECG MONITOR FUNCTION:
The ECG monitor function of the PIC is used to monitor and/or record ECG waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. The PIC also provides output signals for the purpose of sending ECG waveforms to a remote monitor via direct connection, telephone, or radio transmission. Patients may range from neo-natal to adult.

EXTERNAL TRANSCUTANEOUS PACEMAKER FUNCTION:
The external transcutaneous pacing function of the PIC is used for the emergency treatment of hemodynamically compromising bradycardia, bradycardia with escape rhythms that are unresponsive to pharmacologic therapy, refractory tachycardia (supraventricular or ventricular), and bradyasystolic cardiac arrest. Patients may range from pediatric to adult.

NON-INVASIVE BLOOD PRESSURE FUNCTION:
The non-invasive blood pressure function of the PIC is used to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or (occasionally) leg. Patients may range from pediatric to adult.

TEMPERATURE MONITOR FUNCTION:
The temperature monitor function of the PIC is used to make continuous measurements of rectal, esophageal, or surface temperature, and to alarm if the temperature is outside of the limits set by the user. It is used on patients ranging from neo-natal to adult.

PULSE OXIMETER FUNCTION:
The pulse oximeter function of the PIC is used to monitor pulse rate and oxygen saturation of arteriolar hemoglobin, and to alarm if either parameter is outside of the limits set by the user. It is used on patients ranging from neo-natal to adult. Measurements are made non-invasively at remote sites such as a finger, toe, ear lobe, bridge of nose, etc. It is used on patients ranging from neo-natal to adult.

RESPIRATION RATE MONITOR FUNCTION:
The respiration rate monitor function of the PIC is used to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. The patients range from neo-natal to adult. Because the measurement method actually measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It <u>is not intended</u> to be used as an apnea monitor. It is used on patients ranging from neo-natal to adult.