DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1998

Mr. Mark S. Storsved
CardioPulmonary Technologies, Inc.
W260 N9311 Highway J
Colgate, WI 53017

Re: K982487
Meteor Handheld Respiratory Mechanics Monitor
Regulatory Class: II (two)
Product Code: 73 BZC
Dated: July 15, 1998
Received: July 17, 1998

Dear Mr. Storsved:

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.

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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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): K982487

Device Name: CPT, Inc. Meteor Respiratory Mechanics Monitor(s)

Indications for use:

Meteor is a handheld respiratory mechanics graphic monitor intended for use in the hospital clinical environment and transport, either land or air.

It is intended for monitoring mechanically ventilated or supported pediatric and adult patients with tidal volumes greater than 100 ml.

Meteor can be used for either continuous (Meteor 200) or spot check usage (Meteor 100 and 200).

It is not intended to be used as an apnea monitor. No alarms are provided.

Warning: Federal law restricts the use or sale of this device by or on the order of a physician.

Warning: Do not use this device in the presence of flammable anesthetics.

Warning: Do not use this device in the presence of magnetic resonance imaging, MRI, equipment.

Warning: In accessing patient conditions, Meteor is intended only as an adjunct measurement.

Warning: Use of Meteor 100 / 200 in the presence of high concentrations of oxygen, helium-oxygen mixtures and anestetic agents may cause errors in the reported flow measurements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982487

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR801.109)

(Optional Format 1-2-96)