DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Mr. Iihan M. Bilgutay
President
Pace Tech Medical Monitors
510 Garden Avenue North
Clearwater, FL 34615-4126

Re: K970445
Vitalmax 4000 Configured/Vitalmax 4000 Modular/Vitalmax 4100
Regulatory Class: II (Two)
Product Code: 74 MHX
Dated: November 5, 1997
Received: November 10, 1997

Dear Mr. Bilgutay:

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

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

Enclosure

INDICATION FOR USE STATEMENT

In accordance with the FDA new requirement, January 1, 1996 the "Indication For Use", attached, please find the indication for use for all of the devices included under the Premarket notification #K970445. These devices are: Vitalmax 4000 Configured / Vitalmax 4000 Modular / Vitalmax 4100 / Minipack 3000 / Minipack 3100 / Minipack 300 / Vitalmax 800 PLUS.

Vitalmax 4000 Configured / Modular

The Vitalmax 4000 is intended for use in the hospital/clinical environment to measure and monitor the following parameters:

- ECG waveform
- NIBP systolic, diastolic, and mean arterial pressure values (MEAN or MAP)
- Blood oxygen saturation (SpO2 or Pulse oximetry)
- SpO2 waveform
- Pulse (SpO2 and NIBP) signal strength
- Pulse (SpO2 and NIBP) or heart (ECG) rate
- Temperature
- End-tidal Co2 concentration (Et Co2)
- Co2 waveform
- Minimum inspired Co2 concentration (inCo2)
- Respiration rate

Additional options offered are:

- Built-in printer with two channels of annotated waveform or text form of vital signs
- Thoracic impedance respiration
- Invasive pressure waveforms: systolic, diastolic, and mean values (IP, IP2)
- Second temperature channel and Δ temp
- Analog output

The Vitalmax 4000 is available in configured and modular form. The Vitalmax 4000 configured monitor is available in various models which offer the options of Co2, thoracic impedance respiration, printer, and invasive pressures.

The vitalmax 4000 is not intended to be used as apnea monitor or during MRI (Magnetic Resonance Imaging).

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(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970445

Vitalmax 4100

The Vitalmax 4100 CN is intended for use in the hospital/clinical environment to measure and monitor the following parameters:

- ECG waveform
- NIBP systolic, diastolic, and mean arterial pressure values (MEAN or MAP)
- Blood oxygen saturation (SpO2 or Pulse oximetry)
- SpO2 waveform
- Pulse (SpO2 and NIBP) signal strength
- Pulse (SpO2 and NIBP) or heart (ECG) rate
- Temperature
- End-tidal Co2 concentration (Et Co2)
- Co2 waveform
- Minimum inspired Co2 concentration (inCo2)
- Respiration rate
- Nitrous oxide concentration (N2O)

The Vitalmax 4100 G and Vitalmax 4100 A include these additional parameters:

- End-tidal expired Halothane, Enflurane, or Isoflurane agent gas concentration (etHAL, etENF, etISO)
- Inspired Halothane, Enflurane, or Isoflurane agent gas concentration (inHAL, inENF, inISO)
- Fractional inspired oxygen in gas concentration (Fio2 or %o2)

Additional options offered for both models are:

- Thoracic impedance respiration
- Invasive pressure waveform, systolic, diastolic and mean values (IP1, IP2)
- Second temperature channel and teperature difference [Δ temp]
- Built-in strip chart recorder
- Sevoflurane, and Desflurane (etSev, inSev, etDes, inDes)
- Analog Output

The Vitalmax 4100 is not intended to be used as apnea monitor or during MRI (Magnetic Resonance Imaging).

Minipack 3000/3100

The Minipack 3000 and Minipack 3100 are intended for use in the hospital/clinical environment to measure and monitor the following parameters:

- ECG waveform
- NIBP systolic, diastolic, and mean arterial pressure values (MEAN or MAP)
- Blood oxygen saturation (SpO2 or Pulse oximetry)
- SpO2 waveform
- Pulse (SpO2 and NIBP) signal strength

- Pulse (SpO2 and NIBP) or heart (ECG) rate
- Temperature
- End-tidal Co2 concentration (Et Co2)
- Co2 waveform
- Minimum inspired Co2 concentration (inCo2)
- Respiration rate

Additional options offered are:
- Built-in printer with two channels of annotated waveform or text form of vital signs
- Thoracic impedance respiration
- Invasive pressure waveforms: systolic, diastolic, and mean values (IP1, IP2)
- Second temperature channel and Δ temp
- Analog output

The vitalmax 3000 and Vitalmax 3100 are not intended to be used as apnea monitors or during MRI (Magnetic Resonance Imaging).

Minipack 300/ Vitalmax 800 PLUS

The Minipack 300 and Vitalmax 800 PLUS are intended for use in the hospital/clinical environment to measure and monitor the following parameters:
- ECG waveform
- NIBP systolic, diastolic, and mean arterial pressure values (MEAN or MAP)
- Blood oxygen saturation (SpO2 or Pulse oximetry)
- SpO2 waveform
- Pulse (SpO2 or NIBP) signal strength
- Pulse (SpO2 and NIBP) or heart (ECG) rate
- Temperature
- End-tidal Co2 concentration (Et Co2)
- Co2 waveform
- Minimum inspired Co2 concentration (inCo2)
- Respiration rate

Additional options offered are:
- Thoracic impedance respiration
- Add-on 27 ccolumn thermal printer (Minipack 300 Series)
- Built-in printer with two channels of annotated waveform (Vitalmax 800 PLUS)
- Analog output

The Minipack 300 and Vitalmax 800 PLUS are not intended to be used as apnea monitors or during MRI (Magnetic Resonance Imaging).