K990338

SEP 1 1999

510(k) SUMMARY

Modification 510(k) Premarket Notification Submission

NIBP and CO2 Options for the Physio-Control LIFEPAK®12 Defibrillator / Monitor System

1. Submitter's Name: Michael D. Willingham
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2. Name of Device: **NIBP and CO2 Options for the Physio-Control LIFEPAK®12 Defibrillator / Monitor System**

   Classification:

   Noninvasive Blood Pressure Measurement System
   74DXN; 21 CFR 870.1130
   Class II

   Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
   74CCK; 21 CFR 868.1400
   Class II

3. Predicate Device(s)

   Noninvasive blood pressure and carbon dioxide monitoring capabilities has been added to the existing Physio-Control LIFEPAK®12 described in K973486. The intended use and function of the modified Physio-Control LIFEPAK®12 is substantially equivalent to the following devices:

   The Non-invasive blood pressure (NIBP) monitor portion of this 510(k) submission is substantially equivalent to Oscillomate EMS NIBP Monitor Model 9001 (510[k] reference K982135) and the PROPAQ Models 102, 104, 106, (510[k] reference K914838). All devices non-invasively measure the blood pressure of adult and pediatric patients primarily in the emergency care environment.

   The Carbon-Dioxide Gas Analyzer portion of this 510(k) submission is substantially equivalent to MICROCAP (510[k] reference K981114) and NPB-75 (510[k] reference K964239). All devices non-invasively measure the carbon dioxide concentration of the expired and inspired breath and respiration rate.

4.	Device Description	The LIFEPAK®12 defibrillator / monitor series is a complete acute cardiac response system - battery or auxiliary powered defibrillator (manual and AED), monitor, pacemaker, 3 lead ECG, interpretive 12 lead ECG and pulse oximeter. Data can be transmitted by landline or cell phone to computer, fax, printer, or ECG storage system. The users will be Advanced Life Support and Basic Life Support providers in a variety of hospital and pre-hospital settings. Emergency Medical Services users will include Paramedics and Emergency Medical Technicians trained and authorized to respond to medical emergencies. This device will be used in the pre-hospital setting and in the hospital, in critical areas (emergency departments, critical care, operating rooms, etc.) and on general duty floors (e.g. medical/surgical). It will also be used for patient transport (air and ground ambulance, in hospital transport, etc.)
5.	Intended Use	The only modification to the LIFEPAK®12 described in K973486 is the additional capability to non-invasively monitor blood pressure and expired / inspired carbon dioxide. The use of the LIFEPAK®12 capnograph monitor is indicated for a patient that requires the continuous, noninvasive measurement and monitoring of carbon dioxide concentration of expired and inspired breath and respiration rate. The use of the LIFEPAK®12 blood pressure monitor is indicated for a patient that requires the noninvasive measurement of arterial blood pressure using the oscillometric measurement technique, which provides values for the patient's systolic, diastolic, mean arterial pressure and pulse rate.
6.	Comparison of Technological Characteristics	The design, components, storage technology and energy source are similar to its predicate devices. All systems provide a means for interfacing with a patient, collecting parameter specific physiologic data, and processing the data for alarm generation and display of numeric values and waveforms on the LIFEPAK®12 display screen.

7. Testing

The NIBP and CO2 Options for the Physio-Control LIFEPAK®12 is subject to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety testing will be performed by third party agencies to ensure the device complies to applicable industry and safety standards. The LIFEPAK®12 is also subject to testing to assure compliance to the requirements of various standards:

ANSI/AAMI SP-10-1992, Electronic or Automated Sphygmomanometers

IEC 601-2-30; 1995 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Automatic Cycling Indirect Blood Pressure Monitoring Equipment.

IEC 601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety.

EN 864; 1997 Medical Electrical Equipment - Capnometers for use with humans - Particular requirements.

In conclusion, the NIBP and CO2 Options for the Physio-Control LIFEPAK®12 are as safe and effective as the predicate devices and raises no new issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael D. Willingham
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11811 Willows Road NE
Post Office Box 97006
Redmond, WA 98073-9706

Re: K990338
NIBP & CO_2 Options for the LIFEPAK® 12
Defibrillator/Monitor System
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: July 19, 1999
Received: July 20, 1999

Dear Mr. Willingham:

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" (21CFR 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): K990338

Device Name: NIBP & CO_2 Options for the LIFEPAK® 12 Defibrillator/Monitor System

Indications For Use:

NIBP

The LIFEPAK®12 NIBP monitor non-invasively measures blood pressure of the adult and pediatric patients by professionally trained health care providers. It is not designed for continuous, unsupervised monitoring.

EtCO2

The use of the LIFEPAK®12 EtCo2 monitor is indicated whenever professionally trained health care providers determine that a patient requires the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K990338

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

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

(Optional Format 1-2-96)