JAN 1 3 2000

K992584

Premarket Notification [510(k)] Summary

Submitted by: NHE, Corporation
7100 Fernwood St. Suite 1902
Richmond, VA 23228

Contact Person: Sugen Zhang

Device: PE 501 PC-ECG Monitor
Class II

Description: The PE 501 PC-ECG Monitor is a battery-powered, personal computer based electrocardiograph monitoring device. It is designed to acquire, display and record 2 channel ECG signals. The ECG signals are sent to the computer through a serial port and displayed on the computer screen. The ECG signals associated with personal information can be stored into the computer hard disk or floppy disk. Desired segments of the recorded ECG signals can be printed on any Windows compatible printers. The recorded ECG signals can be easily retrieved and can also be transferred to a remote computer with floppy disk, direct machine to machine or E-mail.

Intended Use: Acquiring and displaying 2 channel ECG signals through a personal computer.
Storing ECG signals in computer hard disk and/or floppy disk for a selected time. The standard recording time can be selected from 2 minutes (default) to 100 minutes with 1 minute increment. (Longer recording time up to 48 hours is optional).
Printing the recorded ECG signals on plain papers.
Transferring the recorded ECG signals to a remote computer with floppy disk, direct machine to machine or E-mail.

Substantially Equivalent (SE) to:

ER 700 Series Ambulatory ECG Event Monitor by Braemar Corp., MN,
510(k)# K981394
PC-ECG, by I.P.I. – International Products Inc., the basic model, PC-ECG, of a PC-ECG series of family with no interpretation functions.
510(k)# K963578

Technological characteristics:

All three devices compared use similar technologies to acquire patient's ECG signals, amplify the signals, perform analog-to-digital conversion and store the signals in a digital format. Both PE 501 and ER 720 acquire 2 channel ECG signals but ER 720 stores the signal in a build-in flash memory and PE 501 stores it in computer hard disk. Both PE 501 and IPI PC-ECG store ECG in computer but PE 501 only records 2 channel ECG and IPI PC-ECG records 12 lead ECG signals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2000

Shugen Zhang
President
NHE, Corporation
7100 Fernwood Street, Suite 1922
Richmond, VA 23228

Re: K992584
PE 501 PC-ECG Monitor
Regulatory Class: II (two)
Product Code: MWJ
Dated: November 15, 1999
Received: November 18, 1999

Dear Mr. Zhang:

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,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K992584

Device Name: NHE Corporation PE 501 PC-ECG Monitor

Indications For Use:

The PE 501 PC-ECG is indicated for acquiring and displaying 2 channel ECG signals through a personal computer and transferring the recorded ECG signals to a remote computer.

It is designed for stationary use and is not for ambulatory use. It is intended for use primarily in out-patient clinics. The PE 501 PC-ECG device should be operated by a licensed healthcare practitioner.

(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 K992584

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

(Optional Format 1-2-96)