JAN 18 2000

K981083

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By: Bumedco International Inc.
725 Timber Lane
Shoreview, MN 55126
Tel: (612) 787-0625
Fax: (612) 765-0186

Contact Person: Darrold L. Glanville

B. Device Trade Name: Multifunction K5
Common Name: Blood Pressure Monitoring System
Classification Name: Non-invasive Blood-Pressure Measurement System

C. Predicate Device: Omron Portable Wrist Blood Pressure Kit, Model HEM-608
Vita-Stat Model 8000-C

D. Device Description:

The Multifunction KEITO K5 (K5) is designed to provide the user with measurements of blood pressure, height, and weight, as well as to calculate the Body Mass Index (BMI) and pulse rate. The user is prompted to select a measurement cycle, step onto the K5 platform, and wait momentarily while the measurements and calculations are performed. After the measurements have been taken, the K5 provides the user with the results.

To operate the K5 the user inserts a coin into the coin slot, and steps onto the platform. The user has the option of selecting a partial measuring cycle or a complete cycle. In a partial cycle, weight and height measurements are taken and Body Mass Index calculations are performed in the partial cycle. In a complete cycle, weight, height, blood pressure, and pulse measurements are taken. Body Mass Index is calculated and the W.H.O. blood pressure recommendations are provided. The K5 prints out a ticket containing the results

of the measurements and the recommended ranges for both BMI and blood pressure.

E. Indications for Use:

The Multifunction KEITO K5 is intended to measure height, weight, and blood pressure and to calculate pulse rate.

F. Technological Comparison:

The Multifunction KEITO K5, Vita-Stat Model 8000-C and the Omron Portable Wrist Blood Pressure Monitor have the same type of measurement method as well as provide systolic, diastolic, and pulse measurements.

II. Testing

The pressure system was tested by Physikalisch-Technische Bundesanstalt, to verify the accuracy of the pressure system as compared to a manual sphygmomanometer in accordance with the German's regulations for clinical testing of blood pressure systems (BGBI.IS.759,771 and 1667). The results were evaluated in accordance with the acceptance requirements of the regulation (BGBI.IS.759,771 and 1667) and found to be acceptable.

Additional testing was conducted to determine the correct user height compensation for the K5. The procedure involved testing multiple users of different heights, ages and sex with a manual sphygmomanometer and the K5. The results were computed using statistical methodologies. Based on the results, a formula was developed to compensate for user height during wrist cuff blood pressure measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Darrold Glanville
President
Bumedco International, Inc.
725 Timber Lane
Shoreview, Minnesota 55126

Re: K984083
Trade Name: Multifunction Keito K5, Non-Invasive Blood Pressure System
Regulatory Class: II (two)
Product Code: DXN
Dated: November 5, 1999
Received: November 8, 1999

Dear Mr. Glanville:

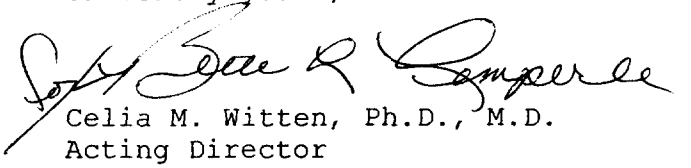
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Multifunction KEITO K5

Sponsor Name: Bumedco International Inc.

Indications for Use

The Multifunction KEITO K5 is intended to be used by adults in order to measure height, weight, systolic and diastolic blood pressures, and to calculate pulse rate.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 984083

Do Not Write Below This Line - Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
Over-The-Counter Use ☐