

MAY 20 1998

**SEIN ELECTRONICS CO.,LTD.**

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 ■ TEL: ANYANG (0343) 21-3201, 21 0389 ■ FAX: (0343) 21 5639

## 510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: \_\_\_\_\_."

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 One Lethbridge Plaza, Suite #4  
 Mahwah, N.J. 07430  
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Date August , 1997

Name of Device:

Proprietary Name: Digital Wrist Blood Pressure Meter, Model SE-330  
 Common or Usual Name: Digital Wrist Blood Pressure Meter  
 Classification Name: System, Measurement, Blood Pressure,  
 Non-Invasive, Systolic and/or Diastolic

The Digital Wrist Blood Pressure Meter, Model SE-330, is equivalent to the OMRON compact wrist blood pressure meter, Model HEM-605.

The SEIN SE-330 Wrist Blood Pressure Meter is a semi-automatic electronic device designed to measure blood pressure and pulse, and in which a compact wrist cuff is used in place of the standard wrist cuff.

Inflation and deflation are accomplished through the use of a manual inflation bulb and solenoid valve respectively.

Blood pressure and pulse are measured using the oscillometric method.

A liquid crystal display of up to six digits is employed to record blood pressure and pulse.

Power is supplied by two lithium batteries (size CR2032)

Built-in memory allows the display of the previously measured blood pressure and pulse values for comparison to current measurements.

An automatic power cut-off feature after one minute of non-use is built into the device to permit saving of energy.

The measuring range of the device is 20--280 mmHg (pressure) and 40--200 pulses per minute with an accuracy of  $\pm 3$ mmHg or 2% of the reading, whichever is greater, for the pressure and  $\pm 5\%$  of the reading for pulse.

The dimensions of the SE-330 Blood Pressure Meter are 58 mm (W) and 70 mm (D) x 23.8 mm (H). The weight of the meter is approximately 110 g including two batteries.

The wrist cuff dimensions are 314.7 mm (l) x 70 mm (w).

Battery life for the device is approximately 150 measurements.

A clinical trial based on the ANSI/AAMI SP-10 1992 Guidance Document for Electronic or Automatic Sphygmomanometers and conducted on 108 patients shows the SE-330 Wrist Blood Pressure Meter to be equivalent to the cuff-stethoscope auscultatory method for determining blood pressure and pulse.

The SEIN SE-330 and OMRON HEM 605 blood pressure meters are similar in that they employ the oscillometric method of measuring, use batteries as their power source, have liquid crystal display of the measurements, and have similar measuring ranges and accuracy. Both devices employ a compact wrist cuff.

Both devices exhibit automatic cut-off power when the instruments are not in use.

Operating and storage environment requirements also are similar.

Differences between the two devices include the following:

The SE-330 uses 2 Lithium batteries, Type CR2032, whereas the HEM-605 uses 2 Alkaline batteries, Type LR03.

The SE-330 has built-in memory enabling display of the previously measured value as well as current measurements. The HEM-605 does not have this feature.

In the SE-330 deflation is controlled by a solenoid valve which keeps velocity constant; the HEM-605 employs a constant release valve system.

Differences between the SE-330 and HEM-605 also include manual repressurization in the SE-330 and automatic repressurization in the HEM-605.

In addition, the weights and dimensions of the two devices are somewhat different.

August 13, 1997  
\_\_\_\_\_  
Date

  
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Tae Young Choi, President

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MAY 20 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Brenda M. Kelly, M.D.  
Executive Vice President,  
Medical and Regulatory Affairs  
The LAHR Consulting Group, Inc.  
One Lethbridge Plaza  
Mahwah, NJ 07430-2113

Re: K973078  
Automatic Digital Wrist Blood Pressure Meter Model SE-330  
Regulatory Class: II (Two)  
Product Code: 74 DPW  
Dated: March 8, 1999  
Received: March 11 1999

Dear Dr. Kelly:

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.

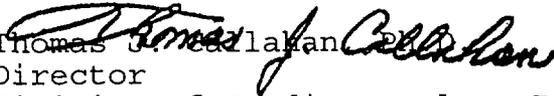
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Brenda M. Kelly, M.D.

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. Colahan, M.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): K 973078

Device Name: Automatic Digital Wrist Blood Pressure Meter -- Model SE-330

Indications For Use: For the measurement of systolic and diastolic blood pressure and pulse rate in adult patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Beate E. Sempere*

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

510(k) Number K 973078

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use x