510K Summary for HEM-9000AI

A. Submitter

Omron Healthcare, Inc.
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Date prepared: August 31, 2005

B. Device

Proprietary Name:	HEM-9000AI
Trade Name:	Non-invasive blood pressure monitor with augmentation index
Regulation Number:	21CFR870.1130
Regulation Name:	Non-invasive blood pressure monitor
Regulation Class:	II
Product Code:	DXN

C. Modified Device

HEM-907XL cleared under K032305

D. Predicate Devices

VP-1000/2000 cleared under K013434
SphygmoCor Px cleared under K012487

E. Device Description

The HEM-9000AI is an oscillometric NIBP measurement and applanation tonometry augmentation index (AI) measurement/calculation device. The HEM-9000AI utilizes both an oscillometric blood pressure detection technology via a cuff wrap at upper arm as well as a tonometry measurement at the radial artery at the wrist. The HEM-9000AI measures the oscillometric signal for NIBP measurement and processes the data through its CPU and algorithm within the device. It provides measurements of systolic and diastolic blood pressures, as well as pulse rate for adult patients with upper arm circumference in the range of 7 - 20 inches (17 – 50 cm). AI information is collected via tonometry by the placement of a set of sensors over the radial artery at the wrist. The tonometer applies pressure and compresses the radial artery until sensors detect the pulse wave (PW). The signal is sent back to the central processor, which separates the superimposed waveform into the ejected wave and the reflected wave components. AI is derived from the pulse wave by calculating the amplitude-ratio of "reflected wave" to "ejected wave" at the radial artery. All

information appears on the device display and can be printed. The device is self-contained, single unit with both oscillsometric and tonometry signal detection built in.

F. Intended Use

The HEM-9000AI is intended to measure systolic and diastolic blood pressure, and pulse rate in adults with an arm circumference of 17-50 cm (7-20 inches) and to measure/calculate radial augmentation index (AI). The HEM-9000AI is intended for use in physician's offices, hospitals, clinics and other medical facilities where non-invasive blood pressure and radial augmentation index measurements/calculations are performed on patients and invasive measurement is contraindicated.

The augmentation index (AI) function of the HEM-9000AI has not been evaluated on patients who have inter-ventricular conduction delays (IVCD).

G. Substantial Equivalence

The HEM-9000AI is intended to measure systolic and diastolic blood pressure and pulse rate in adults with an arm circumference of 17-50 cm (7-20 inches). The HEM-9000AI has the added capability of measuring/calculating augmentation index (AI). The HEM-9000AI uses the same technology as the HEM-907XL in that both devices have the same "Non- Invasive Blood Pressure" (NIBP) algorithm and hardware, including sensors, PCB boards and external cuffs for the NIBP measurement and utilizes the same oscillometric measurement technology. Both devices require that the upper arm be wrapped with a cuff for NIBP measurement. The HEM-9000AI uses the same signal detection and processing system of the HEM907XL.

The HEM-9000AI was tested to AAMI SP-10 performance standards, along with additional AI function testing. The intended use of the HEM-9000AI has not changed in respect to the NIBP of the HEM-907XL.

The HEM-9000AI and the predicate devices VP-1000/2000 and Sphygmocor Px all have the augmentation index (AI) function. The HEM-9000AI uses the same applanation tonometry technology as the VP-1000/2000 and Sphygmocor Px in measuring the pulse wave that is used to calculate the augmentation index. For the augmentation index calculation the VP-1000/2000 uses the pulse wave at the carotid artery of the test subject while the HEM-9000AI and Sphygmocor Px measure the Pulse Wave at the patient's radial artery. Clinical studies of the HEM-9000AI have demonstrated that the calculation of Augmentation Index is highly reproducible. A direct comparison of the displayed radial AI by the HEM-9000AI and the predicate SphygmoCor Px measured on the left radial artery in sequential order on 162 patients demonstrated that on the average, the two devices provide similar results.

H. Performance Testing

The HEM-9000AI was validated by adhering to the tests in the ANSI/AAMI SP10:2002 for NIBP and by additional testing to verify that the radial augmentation indices calculated conformed to the device specification for this aspect. Testing also included Electrical Safety, Environmental, Biocompatibility and EMC. Clinical testing for the NIBP aspect was performed in accordance with the specific requirements established within ANSI/AAMI SP-10:2002. Additional clinical testing was performed to verify the AI specification and accuracy.

I. Conclusions

Omron Healthcare, Inc. has demonstrated through its comparison of performance with the predicate devices that the HEM-9000AI is substantially equivalent to the predicate devices for both the NIBP function and the Augmentation Index function of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2005

Omron Healthcare, Inc
c/o James Li, Ph.D.
General Manager, Business Development
1200 Lakeside Drive
Bannockburn, Illinois 60015-1243

Re: K050233
Device Name: Omron HEM-9000AI Non-Invasive Blood Pressure Monitor with Augmentation Index
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measuring System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 31, 2005
Received: September 1, 2005

Dear Dr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050233

Device Name: HEM-9000AI

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Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Devices

510(k) Number K050233