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510(k) SUMMARY K 991688

MODEL HD-303S
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

1. **COMPANY INFORMATION.** *Name:* Jawon Medical Co., Ltd.
   Address: 7F Jeong Ju Bldg., #1451-38, Seocho-Dong, Seocho-Ku, Seoul 137-070, Korea
   Phone: (011) 82-2-587-4056 *Contact:* Mr. J. N. Kim, Manager

2. **DEVICE IDENTIFICATION.** *Trade Name:* Model HD-303S Wrist Type Digital Blood Pressure Monitor
   Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

3. **PREDICATE DEVICE.** Model WS-200 Automatic Digital Electronic Wrist Blood Pressure Monitor, Nihon Seimitsu Sokki Co., Ltd. - K952494, SE decision 12/28/95.

4. **DEVICE DESCRIPTION.** *General:* The Jawon Model HD-303S is a compact, automatic sphygmomanometer intended for measurement of blood pressure at the wrist. The method of operation is the oscillometric method. The control unit and the cuff are physically integrated into a single wrist-mounted unit. The system is microprocessor controlled and includes an air pump; fuzzy logic to regulate inflation, deflation, and measurement operations; circuitry to detect and process minute pressure oscillations; a six-digit LCD display of systolic and diastolic pressure readings and heart rate; a memory function that stores the previous eight measurement results; and two pushbutton controls.
   Operation: If occlusion of the systolic pulse is not achieved by initial pressurization, cuff pressure is automatically increased in 30 mmHg increments until a proper systolic measurement can be obtained. The device employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. An error message is presented whenever results fail to satisfy preprogrammed accuracy criteria. If cuff pressure starts to exceed 320 mmHg, a high-speed exhaust valve is opened automatically.
   Power: The Model HD-303S is powered by two AAA-size batteries. Power is shut down automatically if the unit remains idle for a period of approximately two minutes.

5. **INTENDED USES.** The Model HD-303S system is indicated for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. Because the device is recommended for use in a home care environment, use should be limited to patients capable of understanding written and/or oral directions.

6. **COMPARISON WITH PREDICATE DEVICE.** The Jawon device has been compared with the Nihon Seimitsu Sokki Co. Model WS-200 Wrist Blood Pressure Monitor. The intended use of the two systems is the same. The principle of operation (oscillometric measurement) and many operating features are identical. The principal differences are that the control unit and cuff are an integral unit in the subject device but separate, requiring that the cuff be connected by the operator in the predicate device, and that operation is controlled by fuzzy logic in the subject device but by conventional automatic methods in the predicate device. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

7. **PERFORMANCE DATA.** The measurement performance of the Jawon system has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the system and components, life testing over 10,005 operational cycles, intra-device variability, environmental integrity under various operating and storage conditions including high and low altitude extremes, and resistance to vibration and shock has been conducted with satisfactory results. Similarly, electromagnetic compatibility and FCC Part 15 compliance studies have been conducted by ONETECH Testing & Evaluation Laboratories, and the device was found to comply with all relevant standards. Software verification and validation have been performed. It is concluded that the subject device complies with all applicable safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

Jawon Medical Co., Ltd.
c/o Ms. Carole Stamp
Responsible Third Party Official
510(k) Program Manager
TÜV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K991688
Wrist Type Digital Blood Pressure Monitor, Model HD-303S
Regulatory Class: II (Two)
Product Code: DXN
Dated: May 14, 1999
Received: May 17, 1999

Dear Ms. Stamp:

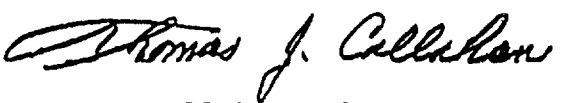
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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, 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): K991688

Device Name: Noninvasive Blood Pressure Measurement System
Model HD-303S Wrist Type Digital Blood Pressure Monitor

Indications For Use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients, i.e., age 18 and above, in a home care environment.

(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 K991688

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)