

NOV 17 1998

510(k) SUMMARY

K 983855

**MODELS HD-1000S AND HD-2000F
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM**

1. **COMPANY INFORMATION.** *Name:* Jawon Medical Co., Ltd.
Address: 2F Seoil B/D, #1451-74, 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:* Models HD-1000S and HD-2000F Fuzzy Type Digital Blood Pressure Monitor
Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN
3. **PREDICATE DEVICE.** A&D Model TM-2650 Automatic Blood Pressure Meter, K895429, SE decision 11/28/89.
4. **DEVICE DESCRIPTION.** *General:* Both models of the Jawon system are compact, automatic sphygmomanometers intended for measurement of blood pressure at the brachial site. All measurements are performed using the oscillometric method. The display unit and the measurement cuff are interconnected by tubing. Both models are microprocessor controlled and include an air pump, an electronic valve to regulate deflation rate, circuitry to detect and process minute pressure oscillations, an LCD display of systolic and diastolic pressure readings and heart rate, and pushbutton controls. Model HD-2000F includes a memory function.
Operation: The subject device employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. The electronic deflation control valve maintains the deflation rate within limits of 3 to 5 mmHg/sec to optimize measurement accuracy.
Power: Both models are powered by four AA-size batteries and contain an indicator to alert the operator when battery charge is weak.
5. **INTENDED USES.** Models HD-1000S and HD-2000F are intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients. Because they are recommended for use in a home care environment, both models are intended to be used by patients capable of understanding written and/or oral directions.
6. **COMPARISON WITH PREDICATE DEVICE.** The two models of the Jawon device have been compared with the A&D Automatic Blood Pressure Meter, Model TM-2650. The intended use of the two systems is the same. The principle of operation (oscillometric measurement) and many operating features are identical. The only substantive difference between the subject and predicate devices is that the predicate device incorporates a thermal printer and the subject device does not. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

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7. **PERFORMANCE DATA.** The measurement performance of the Jawon systems 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, environmental integrity under various operating and storage conditions, and resistance to vibration and shock was conducted by Underwriters Laboratories with satisfactory results. Similarly, electromagnetic compatibility studies have been conducted by ONETECH Testing & Evaluation Laboratories and found to comply with international standards. Software verification and validation have been performed. It is concluded that the subject device complies with all relevant safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAWON Medical Co., LTD.
c/o Carole Stamp
Third Party Official
TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K983855
Noninvasive Blood Pressure Measurement System
Models HD-1000S and HD-2000F
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: October 29, 1998
Received: October 30, 1998

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 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,

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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" (21 CFR 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/dsmamain.html>."

Sincerely yours,

for 
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): K983855

Device Name: Noninvasive Blood Pressure Measurement System
Models HD-1000S and HD-2000F

Indications For Use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients, i.e., age 15 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)

Rita A. Campora

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

510(k) Number K983855

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓