K062462

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Model FT-500(R,L), Model FT-700(R,L)
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

SEP 29 2006

1. COMPANY INFORMATION.

Name : Jawon Medical Co., Ltd.

Address : 1208-12, Sinsang-Li, Jinryang-Eup, Kyungsan-City, Kyungsang-Bukdo, Korea

Phone : 82-53-856-0933

Contact : Mr. J.H.CHO , Senior Engineer, R&D Center

2. DEVICE IDENTIFICATION.

Trade Name : Models FT-500 and FT-700 Automatic Blood Pressure Monitor

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: Models FT-500 and FT-700 of the Jawon system are compact, automatic sphygmomanometers intended for measurement of blood pressure at the brachial site. Models FT-500 and FT-700 employ oscillometric method. All 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 push button controls.

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: Models FT-500 and FT-700 are AC line powered.

5. INTENDED USES.

Models FT-500 and FT-700 of the Jawon system are intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients with age 16 or older and arm circumference range between 9" to 14" (23cm to 36cm).

6. COMPARISON WITH PREDICATE DEVICE.

Models FT-500 and FT-700 of the Jawon device have compared with model of the predicate device, the A&D Automatic Blood Pressure Meter. The intended use of two system is the same. The principle of operation and many operating features are identical. Both the subject device and the predicate device include models in which the control and display console and the cuffs are

constructed as a single unit. All models of the predicate device and Models FT-500 and FT-700 of the subject and predicate devices incorporate a thermal printer.

7. PERFORMANCE DATA.

The measurement performance of the Jawon systems has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-2002 and found to comply filly with the accuracy criteria established in the standard. Non-clinical tests of ANSI/AAMI SP10-2002 were conducted with satisfactory results. Safety testing according to EN60601-1 was conducted by Safety Compliance Ltd and the device fulfills the requirements. Similarly, electromagnetic compatibility studies have been conducted by EMC Compliance Ltd. and found to comply with international standards EN60601-1-2. Software verification and validation have been performed certified. It is concluded that the subject device complies with all relevant safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

Jawon Medical Co., Ltd.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K062462
Trade Name: Models FT-500 and FT-700 Automatic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 14, 2006
Received: September 15, 2006

Dear Mr. Job:

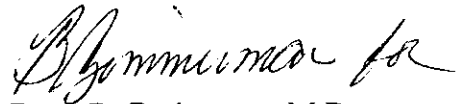
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 or at its Internet address.

Sincerely yours,



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

Enclosure

K062462

Indications for Use

510(k) Number (if known) : _____

Device Name: Noninvasive Blood Pressure Measurement System
Models FT-500(R,L), FT-700(R,L)

Indications For Use:

Noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients with age 16 or older and arm circumference range between 9" to 14"(23cm to 36cm).

Prescription Use_____ AND/OR Over-The-Counter Use__X__

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062462