K013876

SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

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

Infrared Ear Thermometer, Model DX-707

1. SUBMITTER'S IDENTIFICATION

Submitter's Name: Jawon Medical Co., Ltd.

Submitter's Address: 7F Jeong Ju Bldg., 1451-38 Seocho-Dong,
Seocho-Ku, Seoul, Korea

Contact Person: Won-Hee Park/President
TEL: (011) 82-2-587-4056 / FAX: (011) 82-2-588-1937

2. DEVICE IDENTIFICATION

Trade/Proprietary Name: Infrared Ear Thermometer, Model DX-707

Common Name: Radiation Thermometer (Tympanic Thermometer)

Classification Name: Clinical Electronic Thermometer, Class II, 80FLL

3. INFORMATION OF 510(K) CLEARED DEVICES (PREDICATE DEVICES):

- Braun ThermoScan® Instant Thermometer, K# 983295, Braun ThermoScan (Models IRT 3020/3520)
- Microlife Digital Infrared Ear Thermometer, K# 000969, model IR1DA1, Microlife Corporation, 9f, 431 Rui Guang Road, Nei Hu, Taipei 114, Taiwan, Republic of China.

4. DEVICE DESCRIPTION:

The DX-707 Infrared Ear Thermometer is a hand-held, non-sterile, reusable clinical thermometer using an infrared sensor that measures patient body temperature through the opening of the auditory canal. Its operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces.

The DX-707 Infrared Ear Thermometer consists mainly of five parts with the

associated circuit: (1) IR sensor, (2) Micom IC, (3) LCD module, (4) an ambient temperature sensor (thermistor), and (5) Keys, "I/O", "Measure". The DX-707 thermometer is powered by internal DC 3V battery, size CR2032 and it is supplied with probe cover.

5. INTENDED USES:

The DX-707 Infrared Ear Thermometer is intended for the intermittent measurement of human body temperature in home care environment. It is intended for use on people of all ages.

6. STATEMENT OF TECHNOLOGICAL CHARACTERISTICS:

The DX-707 Infrared Ear Thermometer and the predicate devices have the same general design, incorporate similar technology.

The primary function of the DX-707 Infrared Ear Thermometer is the same as the predicate devices. The device is to be used for the measurement of body temperature. The DX-707 raise no new questions of safety and effectiveness.

Jawon Medical Co., Ltd., concludes that the DX-707 Infrared Ear Thermometer is the substantially equivalent to the predicate devices.

7. PERFORMANCE SUMMARY

The DX-707 Infrared Ear Thermometer has been tested and has proven to function in an equivalent manner as the predicate devices. Based on the results of the bench testing the DX-707 Infrared Ear Thermometer is considered safe and effective when used as intended.

Compliance to applicable voluntary standards includes IEC60601-1 and IEC60601-1-2 requirements. In addition, this infrared thermometer meets the requirements established in ASTM Standard E1965-98, "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature". Full responsibility of the conformance of this product to the standard is assumed by Jawon Medical Co., Ltd.

Clinical Results

A comparison study and clinical repeatability testing was performed on the following four ages group; 0-3years, 4-10 years, 11-65 years, and >65 years. Approximately 39% of the patients participating in the study were considered febrile. The comparison study demonstrated that the DX-707 Infrared Ear Thermometer measured ear temperature equivalently to the predicate devices in all age groups. The clinical repeatability is statistically and clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Jawon Medical Company Limited
C/O Mr. John So
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K013876
Trade/Device Name: Infrared Ear Thermometer, DX-707
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 18, 2002
Received: February 20, 2002

Dear Mr. So:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **(if known):** _____

Device Name: Infrared Ear Thermometer, DX-707

Indication For Use:

The Infrared Ear Thermometer, Model DX-707 is intended for the intermittent measurement of human body temperature in home care environment. It is intended for use on people of all ages.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
of Dental, Infection Control,
General Hospital Devices
Number K013874

Prescription Use _____ OR Over-The-Counter Use ___√__

(Per 21 CFR 801.109)