510(K) SUMMARY

K063542

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.

APR 10 2007

The assigned 510(k) number is: _____.

Submitter's Identifications:

Mesure Technology Co., Ltd.

7F, No. 86, Sec. 1, Kwang Fu Road, Sanchung City, Taipei Hsien, Taiwan, R.O.C.

Contact: Ph. D. John, Chen / General Manager

Date of Summary Preparation: October 20, 2006

1. Name of the Device:

   Wireless temperature monitor, model ST323C and ST323F.

2. Information of the 510(k) Cleared Device (Predicate Device):

   Wireless thermometer monitor; model ST313C and ST313F (K023956).

3. Device Description:

   The ST323C and ST323F are the wireless temperature monitor intended to be worn at left arm to monitor the armpit temperature continuously.

   ST323C and ST323F is composed of two operational parts, the receiver and transmitter. The receiver is the main operation unit on which, the LCD display control circuit and the main operation keys are included. And the transmitter was constructed with the thermo sensor, measuring circuit, and the signal communication unit and is to be worn at left arm for the continuous armpit temperature monitor.

   For the monitoring operation, both receiver and transmitter shall be switched on. Sooner after these two parts are switched on, the wireless signal communication will be set up between receiver and transmitter. The temperature monitoring signal measured at armpit will be continuously indicated on the LCD of receiver every 15 sec.

   This system uses a 3.0V DC battery for operation of complete system. Whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays 'Low battery' in LCD display. Regarding the performance of ST323C and ST323F, it was designed and verified according to the US standard ASTM E1112-00.

4. Intended Use:

   The Wireless thermometer, model ST323C and ST323F is the battery-operated electronic devices with intended use of measuring human body temperature precisely. This device is reusable and intended for armpit temperature measurement for the person of all age.

5. Comparison to the 510(k) Cleared Device (Predicate Device):

   The Wireless thermometer, model ST323C and ST323F is substantially equivalent to the Mesure model ST313C and ST313F (K023956).

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

   Compliance to applicable voluntary standards includes ASTM E1112: 2000, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

7. Discussion of clinical report for measurement accuracy:

   Clinical test for the comparison of measurement accuracy between ST323C and Mesure digital thermometer ST8A3C are included. The measurement was taken by both ST323C and ST8A3C at armpit location for the children less than eight years old according to the method recommended in ASTM-E1965.

   The result of clinical report indicates that ST323C is suitable for the indication of intended use.

8. Conclusions

   The Mesure / Wireless thermometer, model ST323C and ST323F, has the same intended use and technological characteristics as the cleared device of Mesure model ST313C and ST313F. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Chen
General Manager
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Sanchung City, Taipei Hsien
TAIWAN, R.O.C.

APR 10 2007

Re: K063542
Trade/Device Name: Wireless Temperature Monitor/Model: ST323C and ST323F
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 6, 2006
Received: March 19, 2007

Dear Mr. Chen:

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) 276-0115. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: Wireless temperature monitor / Model: ST323C and ST323F.

Indications For Use:

The wireless temperature monitor, model ST323C, ST323F are the battery-operated electronic devices with intended use of measuring human body temperature precisely. This device is reusable and intended for armpit temperature measurement of the person of all age.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for APW

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K063542