OCT 1 8 2004

K042627

510(K) SUMMARY

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, and the relevant 510(k) submission guidance.

The assigned 510(k) number is: _____.

Submitter's Identifications:
Company: Mesure Technology Co., Ltd.
Address: 7F, No. 86, Sec. 1, KwangFu Road, Sanchung City, Taipei Hsien, Taiwan, R.O.C.
Contact person: John Chen / Ph. D.

1. Name of the Device:
   Ear Thermometer / Models ST61, ST62, ST63, ST64 and ST65

2. Information of the 510(k) Cleared Device (Predicate Device):
   Ear Thermometer Model ST613C & ST613F.(K011254)

3. Device Description:
   The Mesure ear thermometer, models ST61, ST62, ST63, ST64, and ST64, are the handheld electronic thermometers that measures the temperature through the opening of the auditory canal by using a thermopile as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC) – controlled circuit, which is considered the hard-wire control instead of programmable control.

   From the construction point of view, the ear thermometer comprises of a thermopile for the measuring sensor, a reference thermistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermopile sensor detect the ear canal temperature through the infrared.

   This system uses a 3.0 V 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 ST61, ST62, ST63,ST64 and ST65, they were designed and verified according to the US standard ASTM E 1965-00.

4. Intended Use:
   The device measures the body temperature from the auditory canal of of a patient by means of an infrared sensor coupled with an electronic signal amplification, conditioning and digital LCD (display) unit. The device is reusable and intended for home use on people of all ages.

5. Comparison to the 510(k) Cleared Device (Predicate Device):
   Since the new models ST61, ST62, ST63, ST64 and ST65 were developed from the cleared device ST613C and ST613F through the design control procedures of Measure Technology Co., Ltd. with only the small change in dimension, device housing, and some non-performance and safety related features, the new device is substantial equivalence to that of device being modified, ST613C and ST613F

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance to applicable voluntary standards includes ASTM E1965: 2000, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

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7. Conclusions

The Mesure ear thermometer thermometer, models ST61, ST62, ST63, ST64, and ST65 have the same intended use and technological characteristics as the cleared device of Measure's model ST613C and ST613F. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate 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

OCT 18 2004

Dr. John Chen
General Manager
Mesure Technology Company Limited
7f, 86, Sec.1, Kwang Fu Road
San Chung City, CHINA (TAIWAN) 241

Re: K042627
Trade/Device Name: Ear Thermometer, Models ST61, ST62, ST63, ST64 and ST65
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 25, 2004
Received: September 27, 2004

Dear Dr. 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.

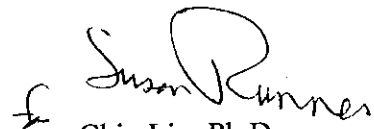
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.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

K042627

Indications For Use

510(k) Number (if known):

Device Name: Ear Thermometer, Models ST61, ST62, ST63, ST64 and ST65..

Indications For Use:

The device measures the body temperature from the auditory canal of of a patient by means of an infrared sensor coupled with an electronic signal amplification, conditioning and digital LCD (display) unit. The device is reusable and intended for home use on people of all ages.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042627