

K070578

510(K) SUMMARY

JUL 11 2007

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.

The assigned 510(k) number is: _____.

Submitter's Identifications:

Zen Strong Medical Technology Co., Ltd.
6F No. 88, Ning Jin St., Keelung, Taiwan, R.O.C.

Contact: Cheng Roei-Sheng

Date of Summary Preparation: February 15, 2007

1. Name of the Device:

Clinical thermometer / Model ZSDT-XXX Digital thermometer and ZSET-XXX Infrared thermometer; where "XXX" means the designation of different device housing.

2. Device classification:

Trade/Device Name: Clinical thermometer / Model ZSDT-XXX Digital thermometer and ZSET-XXX Infrared thermometer; where "XXX" means the designation of different device housing.

Regulation Number: 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

3. Device Description:

A> ZSDT-XXX Digital thermometer.

The digital clinical thermometer, models ZSDT-XXX Series, are the electronic thermometers by using a thermistor 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 digital thermometer comprises of a thermistor for measuring sensor, measuring circuit for the measurement of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

This system uses a 1.5V/DC AG3 or SG3 Alkaline 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 ZSDT-XXX, it was designed and verified according to the US standard ASTM E 1112-00.

B> ZSET-XXX Infrared thermometer.

The infrared thermometer, models ZSET-XXX, 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(2xAAA batteries) 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 ZSET-XXX, they were designed and verified according to the US standard ASTM E 1965-2002.

4. Intended Use:

The clinical thermometer / model ZSDT-XXX digital thermometer measures the body temperature of a patient by means of a sensor (transducer) coupled with an electronic signal processor and digital LCD (display) unit. The device is reusable and intended for oral, rectal, or armpit temperature measurement for home use on people at all ages.

The clinical thermometer / model ZSET-XXX infrared thermometer are the battery-operated electronic devices with intended use of measuring body temperature from the auditory canal of a patient by means of an infrared sensor coupled with electronic signal amplification, conditioning and a digital LCD (display) unit. The device is a reusable and intended for home use on people at all ages.

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

- The digital thermometer model ZSDT-XXX is to be compared to the Mesure digital thermometer, model ST8A3C (K042013).
- The infrared thermometer model ZSET-XXX is to be compared to the Mesure ear thermometer, model ST613C (K011254).

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

Compliance to applicable voluntary standards includes ASTM E1112: 2000, ASTM E1965: 2002, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement. All of the required conformity reports were included on the 510(k) submission documents.

7. Discussion of clinical report for measurement accuracy:

The clinical report for the measurement accuracy comparison as required by ASTM E1965: 2002 is provided for ZSET-XXX and ST613C.

8. Conclusions

The Clinical thermometer / Model ZSDT-XXX Digital thermometer and ZSET-XXX Infrared thermometer has the same intended use and technological characteristics as the cleared device of Mesure model ST8A3C digital thermometer (K0402013) and ST613C ear thermometer (K011254). 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. Therefore, it is reasonable to conclude that Clinical thermometer / Model ZSDT-XXX Digital thermometer and ZSET-XXX Infrared thermometer are substantially requirement to the chosen predicate devices.



JUL 11 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cheng Roei-Sheng
Official Correspondent and President
Zen Strong Medical Technology Company, Ltd.
6F No. 88, Ning Jing Street
Keelung, R.O.C.
TAIWAN

Re: K070578
Trade Name: Clinical Thermometer, Models ZSDE-XXX and ZSET-XXX
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 19, 2007
Received: June 19, 2007

Dear Mr. Roei-Sheng:

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.

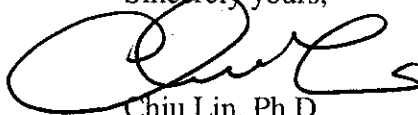
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
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: Clinical thermometer / Model ZSDT-XXX Digital thermometer and ZSET-XXX Infrared thermometer; where "XXX" means the designation of different housing..

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ✓
(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

[Signature]
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

[Signature]
7/11/07

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