K101043

JUL 21 2010

Changshan Estar Electronics Co., LTD.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.
Date of summary was prepared: June 12, 2010

Device

Trade name: ECT digital thermometer
Common/Usual name: Digital thermometer
Classification name: Clinical electronic thermometer
Medical specialty (Panel): General Hospital
Regulation number: 880.2910
Product Code: FLL
Classification: Class II

Predicate devices

Omrom MC-245 (K091676), Omron Healthcare Incorporated
Basic Digital Thermometer, model DT-02 (K041694), Hangzhou Hua'an Medical & Health Instrument Co. Ltd.

Indication for Use

ECT digital thermometer is an electronic clinical thermometer which is intended to measure the human body temperature in regular mode orally, rectally or underarm. The device is reusable for clinical or home use on people of all ages.

Device description:

The ECT digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of the temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

This thermometer uses a DC 1.5V battery for operation of complete system whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays '▼' in LCD display.

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Statement of substantial equivalence

The ECT digital thermometer is similar in design and intended use to the MC-245 and DT-02, differing only in physical dimensions, display resolution, battery replacement method. They use a thermistor to measure temperature and comprise of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

While there are minor differences in performance specifications of the thermometers, these differences do not alter the intended use function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **ESTAR** believes that the **ECT digital thermometer** is substantially equivalent to legally marketed devices currently in commercial distribution.

Summary of Non-Clinical Testing

The ECT digital thermometer complied with the requirements of ASTM E1112-00 (2006) standard specifications, as well as IEC 60601-1(2005), ISO 10993-5(2009) and ISO 10993-10(2002) requirements. Bench testing confirmed the temperature range, accuracy, operating environment, storage environment, resolution, readability and repeatability. For all body contacting materials, analysis is made that the identical materials have been used in other legally marketed devices under the same use conditions.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Changshan Estar Electronics Co., Ltd. concludes that, ECT Digital thermometer is substantially equivalent to predicate devices as described herein.

The SE comparison of the **ECT digital thermometer, DT-02 (K041694)** and **MC-245 (K091676)**

	ECT digital thermometer	DT-02(K041694)	MC-245(K091676)
Intend use	To measure the human body temperature in regular mode orally, rectally or underarm. The device is reusable for clinical or home use on people of all ages.		To measure the body temperature either oral, axillaries (under arm) and rectal
Measurement method	Human temperature is detected by thermistor and calculated		
Measurement area	Oral, rectum, underarm		
Probe tip	Rigid		
Measurement range	90.0 ~ 109.9°F 32.0 ~ 42.9°C	89.6 ~ 109.4°F 32.0 ~ 43.0°C	89.6 ~ 107.6 °F, 32.0 ~ 42.0 C
	The model switchs the display unit (°F, °C) alternately		
Display resolution	0.1°F/°C	0.01°F/°C	4 digits(0.1°F/°C increments)
Accuracy	±0.2 °F/ ±0.1 °C	±0.05°C	±0.2 °F/ ±0.1 °C
Over measurement range	Temp. < 90 °F (32°C) display <Lo> for low (too low) Temp. > 109.9 °F (42.9°C) display<Hi> for high (too high)		
Response time	Approx. 1 min (oral) Approx. 3 to 5 min (underarm) Approx. 1 min (rectal)	Approx. 1 min. (oral) Approx. 100 sec. (underarm) Approx. 1 min (rectal)	Approx. 80 sec (oral) Approx. 2 min (underarm) Approx. 1 min (rectal)

(Continuous) The SE comparison of the **ECT digital thermometer, DT-02 (K041694)** and **MC-245 (K091676)**

	ECT digital thermometer	DT-02(K041694)	MC-245(K091676)
Display	Reading value is displayed on LCD with 3 1/2 digits (0.1 increments)	Reading value is displayed on LCD with 4 digits (0.01 increments)	Reading value is displayed on LCD with 4 digits (0.1 increments)
LCD Dimension	33 x 23 mm	15.5 x 6.5 mm	
Beep	When thermometer turn on and after completion of measurement	Beeper sound at peak temperature	1 beep when power on 3 beeps after measurement completed
Power source	Alkaline-Magnesium button battery, DC 1.5V/1.55V(LR41)		
Power consumption	0.15 mW		0.1 mW
Battery life	Approx. 1 year(using time:10 min/day	Approx. 200 h for continuous operation	Approx. 5,000 readings (if used 10 minutes per day)
Weight (with battery)	Approx 1/3 oz(10.5g)	Approx 1/3 oz(10.5g)	Approx 1/3 oz(11g)
Dimension	10(H) x 13(W) x 128 (L) mm	10(H) x 18(W) x 127(L) mm	19.4(W) x 132.5 (L) x 10.0 (D) mm
Operating environment			
Temperature	– 41 ~ 104 °F (5 ~ 40 °C)	– 41 ~ 113 °F (5 ~ 45 °C)	50 ~ 104 °F(10 ~ 40 °C)
Relative humidity	15 ~ 95%	≤ 80 %	35 ~ 85%
Storage environment			
Temperature	– 14 ~ 128 °F (– 10 ~ 60 °C)	77 ~ 131 °F (25 ~ 55 °C)	4 ~ 140 °F(– 20 ~ 60 °C)
Relative humidity	≤ 85 %	≤ 80 %	10 ~ 95%

(Continuous) The SE comparison of the **ECT digital thermometer, DT-02 (K041694)** and **MC-245 (K091676)**

	ECT digital thermometer	DT-02(K041694)	MC-245(K091676)
Automatic shut-off	YES/ After about 10 min		Approx. 30 minutes after use or 3 minutes when not been used
Memory	Recalls last temperature		
Waterproof	YES		
Materials	Probe: 316 S.S., Case: ABS		
Clean	By 70% isopropyl alcohol or soap and water		
Performance tested	ASTM E1112 IEC 60601-1 ISO 10993-5 / ISO 10993-10		

End of summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Mr. Jacob Chang
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JUL 21 2010

Re: K101043
Trade/Device Name: ECT Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 23, 2010
Received: June 23, 2010

Dear Mr. Chang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K101043

Device Name: **ECT digital thermometer**

Indications for Use:

ECT digital thermometer is an electronic clinical thermometer which is intended to measure the human body temperature in regular mode orally, rectally or underarm. The device is reusable for clinical or home use on people of all ages.

Prescription Use _____ Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) AND/OR (Part 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

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