



Food and Drug Administration  
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February 9, 2016

Guangdong Biolight Meditech Co., Ltd  
% Ms. Diana Hong  
General Manager  
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P.O. Box 120-119  
Shanghai, 200120  
CHINA

Re: K152739

Trade/Device Name: Electronic Thermometer  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: January 25, 2016  
Received: February 1, 2016

Dear Ms. Hong:

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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

 Tina Kiang  
-S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152739

Device Name

Electronic Thermometer, Model WT1 and WT2

Indications for Use (Describe)

Electronic Thermometer is intended for measuring and monitoring human body temperature orally and/or under arm for adult, pediatric and infant. It can be used in healthcare facility and home.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K152739

1. Date of Preparation: 1/25/2016
2. Sponsor Identification

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3. Designated Submission Correspondent

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#### 4. Identification of Proposed Device

Trade Name: Electronic Thermometer

Common Name: Clinical electronic thermometer

Model(s): WT1, WT2

##### Regulatory Information

Classification Name: Clinical electronic thermometer

Classification: Class II

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Review Panel: General Hospital

##### Intended Use Statement:

Electronic Thermometer is intended for measuring and monitoring human body temperature orally and/or under arm for adult, pediatric and infant. It can be used in healthcare facility and home.

##### Device Description

The proposed device, Electronic Thermometer, is a handheld device with battery power supply, intended for measuring and monitoring human body temperature orally and/or under arm for adult, pediatric and infant. It can be used in healthcare facility and home. There is no specific use of this device other than temperature measurements, including conversion of temperatures.

The proposed device is available in two models, which are WT1 and WT2.

##### Similarities between models:

- a. Both of them incorporate a temperature sensitive sensor
- b. Both of them can measure and monitor human body temperature under arm;
- c. Neither the WT1 nor WT2 has display function, the measured or monitored temperature will be transmitted to a mobile application, Temp Sitter, installed under iOS system via the blue tooth to display the measured and monitored temperature;

##### Differences between models:

- a. WT1 has an automatic power on/off feature;
- b. WT1 can be used with an adhesive tape, which could be fix the thermometer under arm for measuring and monitoring;
- c. WT2 can be used with a designated probe cover;
- d. WT2 can be used for measurement of oral temperature.

5. Identification of Predicate Device(s)

510(k) Number: K132514

Product Name: Kinsa Smart Thermometer

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- ISO 80601-2-56 First Edition 2009-10-01, Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	FLL	FLL
Regulation Number	21 CFR 880.2910	21 CFR 880.2910
Intended Use	Electronic Thermometer is intended for measuring and monitoring human body temperature orally and/or under arm for adult, pediatric and infant. It can be used in healthcare facility and home.	The Kinsa Smart Thermometer is intended to measure the human body temperature orally, rectally, or under the arm, and the devices are reusable for clinical or home use on people of all ages
Measurement Site	orally and/or under arm	orally, rectally, or under the arm
Feature	Compatible with iOS Mobile Device via	Compatible with iOS Mobile Device via

	wireless connection	wire connection
	Display in mobile application, no display on device	Display in mobile application, no display on device
Component	Temperature Sensitive Sensor	Temperature Sensitive Sensor
	Plastic Housing	Plastic Housing
	Circuit Board	Circuit Board
	No Cable	Cable
	Battery (button cell)	Mobile Device Power Supply
Accessories	Adhesive tape (WT1)	No
	Container (WT1)	No
	Probe cover (WT2)	No
Range	25.00°C~45.00°C	35.00°C~42.00°C
Accuracy	±0.1°C 25.00°C~34.99°C	Not Claimed ±0.1°C 35.00°C~42.00°C
	±0.05°C 35.00°C~38.50°C	
	±0.1°C 38.51°C~45.00°C	
Precision	4 numeric digits displayed in 0.01 degree increments	4 numeric digits displayed in 0.01 degree increments
Response Time	5 minutes	15 seconds
Unit	°C and °F	°C and °F
Patient contact materials	Stainless Steel, S216 Polycarbonate (PC), 2458 Silicone, TPE Non-Woven Cloth Medical Melt Adhesive	Stainless Steel Thermoplastic rubber Acrylonitrile butadiene styrene
Biocompatibility	No Cytotoxicity No Sensitization Irritation-negligible	Comply with ISO 10993-5 and ISO 10993-10
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2

Discussion of Main Differences:

The proposed device can only measure orally and/or under arm, however, the predicate device can additionally measure rectal temperature. The intended sites have been communicated in the user manual, and this will not affect the intended use of the device; the proposed device connects with the iOS device through wireless method, however, the predicate device connects the iOS device through cable. Risk analysis and associated verification has been performed that the wireless feature is acceptable; In addition, the proposed device has a longer response time, however, this time is still acceptable and communicated in the User Manual.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.