July 11, 2018

Xuzhou Yongkang Electronic Science Technology Co., Ltd
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
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Beijing, 102401
China

Re: K180314
Trade/Device Name: Infrared Thermometer, Model(s): YK-IRT1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 12, 2018
Received: April 16, 2018

Dear Ray Wang:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180314

Device Name
Infrared Thermometer
Model(s): YK-IRT1

Indications for Use *(Describe)*
The Infrared thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

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.

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Tab #7 510(k) Summary

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

The assigned 510(k) Number: K180314

1. Date of Preparation: 07/10/2018

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Infrared Thermometer
Common Name: Infrared Thermometer
Model(s): YK-IRT1

Regulatory Information
Classification Name: Clinical electronic thermometer
Classification:II
Product Code:FLL
Regulation Number: CFR 880.2910
Review Panel:General Hospital;

Intended Use Statement:

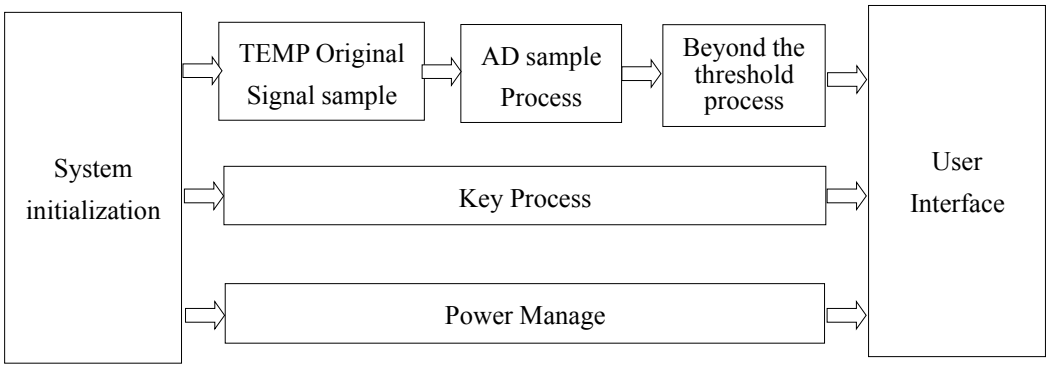
The Infrared thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

Device Description

The Infrared thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.
The Infrared thermometer has the following features

1) 1 second measure the temperature.
2) Sensor measurement technology.
3) Automatically power-off, if left idle for 60 seconds.
4) One-key measurement.
5) Prompt for fever.
6) Stores 12 sets recent measurement data for your data contrast.
7) Safety by infrared measuring.

Fig 7-1 Working Frame of YK-IRT1



YK-IRT1 is divided into System initialization module, Temperature Signal sample module, AD (Analog

signal/Digital signal) sample process module, Beyond the threshold process module,Key processing module, Power Manage
module,User Interface module.

a. System initialization

System initialization setting mainly includes the following aspects:
a) power on the device;
b) Initialize MCU (Microprogrammed Control Unit) System Configure;
c) Initialize Power Manage;
d) Initialize Infrared sensor;
e) Initialize LCD display;
f) Initialize TEMP arithmetic;
g) Get into working status.
This part mainly initializes the system and relevant part, so that the whole system enters into the ready state.

b. Temperature Signal sample：

In this module, The MCU control the sensor probe, then AD module get the sample from the infrared sensor. In this module, the AD module will sample the infrared ray signal which will be count in the TEMP arithmetic.

c. AD (Analog signal/Digital signal) sample process：

This part is mainly to realize the processing of sensor data, is the implementation of TEMP algorithm.

d. Beyond the threshold process：

This part is mainly to determine of temperature value is out of the threshold.Green backlight: Below 37.5 ℃, indicating temperature is normal;Yellow backlight: Between 37.6~38.0℃, indicating temperature is on the high side（should pay attention to the temperature）; ed backlight: over 38.1℃, indicating fever(should see a doctor as soon as possible)

e. Key processing：

Key handling part mainly deals with user actions by scanning keys, and the configuration information which the user sets up is stored.

f. Power Manage

Power module implements the functions include power on and off the device, get the Battery Voltage. In this part, Power module power all the modules, include MCU, infrared sensor, LCD and other related modules.
If the user has no operation for it after 60 seconds , the device will be power off.

g. User Interface

UI interface is mainly used to display some information such as TEMP value and Measuring positional symbols. And the different interfaces will be displayed according to the user’s action when the key will be press.

5. Identification of Predicate Device(s)

Predicate Device ：

510(k) Number: K140681
Product Name: Belter Infra-red Ear Thermometer
Model Name: TE-68
Manufacturer:
Shenzhen Belter Health Measurement and Analysis Technology Company, Limited

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:

a. IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
b. IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
c. ISO 80601-2-56, Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
d. IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment-Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
e. ASTM E1965-98, Standard Specification For Infrared Thermometers For Intermittent Determination Of Patient Temperature.
f. ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
g. ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

7. Clinical Test Conclusion

The clinical trial was performed according to ASTM E1965-98, Standard Specification For Infrared Thermometers For Intermittent Determination Of Patient Temperature.
The purpose of the clinical trial was to evaluate the clinical measurement accuracy and clinical repeatability of the YK-IRT1 Infrared Thermometer.

There are three group of subjects (161 in total) are selected for this trial.The number of subjects is determined by referring to the requirements of Term X2.3.1 of the Appendix to standard ASTM E1965-98 , i.e. 3 age groups and at least 30 subjects for each group.

The test adopts infrared thermometer (YK-IRT1), of which the measured results are compared to the

calibrated oral mercury-in-glass thermometer used in the hospital.

Also, the ear temperature results are compared to the Braun PRO 6000 ear thermometer of the control group, and the forehead temperature results are compared to the TVT-200 forehead thermometer of the control group.

The patient who has unclean external auditory canal and lots of earwax, or has hearing aid in the cochlea, or of whom the external auditory canal has trauma, inflammation and malformation or is under medicating, are excluded; patient who takes medicine that may lead to body temperature change or accepts local cryotherapy or hyperthermia is excluded; patient who has unconsciousness or mental disorder is excluded.

Apply control test method to verify the ear temperature measurement results of the test group by using infrared thermometer, and compare them with the measurement results of the control group by using oral mercury thermometer, thus verifying the clinical accuracy and repeatability.

Clinical accuracy index: compare the measured ear/forehead temperatures of the test group with the measured temperature of the control group by using oral mercury thermometer, and calculate the error standard deviation and mean absolute deviation.

Clinical measuring repeatability: compare the measured temperatures of the test group/control group with that of oral mercury thermometer of the control group, and calculate the result by referring to formula X2.2 and X2.3 in the Appendix to standard ASTM E1965-98.

Clinical Trail Results

Item			Test group YK-IRT1 infrared thermometer
Ear temperature	0~1 year old	Clinical standard deviation	0. 13
		Mean absolute deviation	0. 11
		Clinical repeatability	0. 06
	1~5 years old	Clinical standard deviation	0. 16
		Mean absolute deviation	0. 13
		Clinical repeatability	0. 06
	Above 5 years old	Clinical standard deviation	0. 14
		Mean absolute deviation	0. 11
		Clinical repeatability	0. 06

Base on the trial results and statistical analysis, it shown that the clinical accuracy and and clinical repeatability of the YK-IRT1 Infrared Thermometer are all conform to the values specified in ASTM E1965-98 and no adverse event or side effect is found during the clinical trial.

8. Substantially Equivalent (SE) Comparison

Table 7-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Device name	YK-IRT1 Infrared Thermometer	TE-68 Belter Infra-red Ear Thermometer
Classification Name	Clinical electronic thermometer	Clinical electronic thermometer
Product Code	FLL	FLL
Regulation Number	CFR 880.2910	CFR 880.2910
Comparison Statement	**The proposed device has same classification information as the predicate device.**	
Intended Use	The Infrared thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.	The Belter Infra-red Ear thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.
Comparison Statement	**The proposed device has similar intended use as the predicate device.**	
Main Unit Technical Specifications		
Measurement Range	34.0℃～43.0℃	32.0℃ -42.2℃ （ 89.6℉-108.0℉）
Accuracy	< 35.0℃ and >42.0℃ : ±0.3℃ 35.0℃～ 42.0℃ : ±0.2℃	±0.2℃ (36℃≤t<39) ; ±0.3℃other range
Response time	1 sec.	1 sec.
Measurement place	ear	ear
Measuring interval	About 6 s	3s
Scale selection	℃/℉	℃/℉
Display screen	LCD	LCD
Memory	Save last measured 12 memories	10 sets
Fever Prompt	Yes	Yes
Disposable probe cover	No	No

Back light	Yes	optional
Buzzer	Yes	Yes
Auto power-off	60 seconds after no operation	Yes while no operation
Power supply	2×1.5V AAA	2 x 1.5V AAA
Sterile	No	No
Single Use	No	No
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device.**	
Applied Standards:		
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10
Electrical Safety	IEC60601-1 IEC60601-1-11	IEC60601-1 IEC60601-1-11
EMC	IEC60601-1-2	IEC60601-1-2
Performance	ISO 80601-2-56 ASTM E1965-98	ISO 80601-2-56
Comparison Statement	**The proposed probe has same applied Standards with the predicate device.**	

9. Substantially Equivalent (SE) Conclusion

The subject device has same classification information, same intended use, same indication for use, similar product design, similar specification, same safety elements, similar applied Standards as predicate device.

The differences are included as followings:

Analyse 1：The differences in technological characteristics do not raise different questions of safety and effectiveness and the performance data demonstrate equivalence.

Conclusion: The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.