510(k) Summary

1. Submitter

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2. Name of Device

Trade Name: Digital Thermometer, Model 2180
Common/Usual Name: Digital Thermometer
Regulation Number: 21 CFR 880.2910
Classification Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL

3. Predicate Device

Device Name	510(k) Number	Decision Date
K-jump Health Co., Ltd.		
Basal Digital Thermometer	K141505	8/26/2014

This predicate has not been subject to a design-related recall.

4. Device Description

The Digital Thermometer consists two parts. The thermometer probe part is a compact, small, light-weight, and battery-powered unit with thermometer sensor for oral temperature measurements. The thermometer probe must be connected to a compatible mobile phone device through its headphone jack for displaying measured temperatures.

The mobile application could be conducted for operation and display temperature measurement when the Digital Thermometer connects with mobile device. The mobile application can be conducted on iOS operating system and Android operating system of mobile device.

The mobile application could perform the functionality on mobile device screen including measurement activity, historical data activity, trend activity, basic setting and initial setting activity.

5. Indications for Use

The Digital Thermometer is intended to measure oral temperature of human body. It can be used in home environment or at a doctor's clinic. It is indicated for use by people of all ages.

6. Technological Characteristics

The Digital Thermometer uses a thermistor sensor to detect the thermal energy from human body. The sensor in the thermometer detects temperature change and transfers to the proper electronic signal. The electronic signal could be received and converted to the temperature reading. The measured data will be displayed on the screen of a mobile device. The technological characteristics of Digital Thermometer have no significant difference with predicate device.

7. Comparison of technological characteristics with Predicate Device

The Digital Thermometer is substantially equivalent to the predicate devices, K141505, the Basal Digital Thermometer. The comparison of their technological characteristics is summarized in the table below.

Characteristics	Digital Thermometer	Basal Digital Thermometer
510(k) Number	K170262	K141505
Intended Use	Similar	Similar
Technology		
Measurement method	Thermistor detection	Thermistor detection
Feature	Compatible with iOS / Android Mobile Device via headphone jack connection	Compatible with iOS/Android Mobile Device via headphone/NFC connection
	Measured data display on the screen of mobile device	Measured data transfer to mobile device
Function		
Measuring Range	32.0℃~43.9℃	32.00℃~43.90℃
C/F Switchable	Yes	Yes
Performance		
Display	3 1/2 digits on the screen of a mobile device	4 1/2 digits on the LCD of medical device
Display Resolution	0.1℃ (℉)	0.01℃ (℉)
Measuring accuracy	±0.1℃(35.5℃ to 42.0℃); ±0.2℃(other range)	±0.1℃(34.00℃ to 42.00℃); ±0.2℃(other range)
Low battery detection	Yes	Yes
Memory	1 set memory	40 set memory
Environmental		
Operating condition	10℃ ~40℃ (50 ~ 104℉) 15%-95% RH	5℃ ~40℃ (41.0 ~ 104℉) 15%-95% RH
Storage condition	-20℃ ~50℃ (-4.0 ~ 122℉) 15%-95% RH	-25℃ ~55℃ (-13.0 ~ 131℉) 15%-95% RH

Characteristics	Digital Thermometer	Basal Digital Thermometer
Material		
Component materials	Stainless Steel, Acrylonitrile butadiene styrene	Stainless Steel, Acrylonitrile butadiene styrene
Biocompatibility	No Cytotoxicity No Sensitization & Irritation-negligible	No Cytotoxicity No Sensitization & Irritation-negligible
Power	Internal power (one SR41 battery)	Internal power (one CR2032 battery)
Physical		
Dimensions	87.5 x 14.2 x 8.7 mm	125.5 x 34 x 9.6 mm
Weight	6g (with battery)	24g (with battery)

➢ Discussion of Main Differences:

The Digital Thermometer connects to the mobile device through headphone jack. The measured data will be displayed on the screen of a mobile device. The predicate device could display measured data on the device and transfer measured data to a mobile device.

While connected with mobile device, the usage of Digital Thermometer is identical to the predicate device. Risk analysis, software validation and associated verification have been performed and demonstrated that the display feature of the subject device is acceptable;

8. Performance Summary

The performance of the Digital Thermometer is verified and validated to comply with following recognized standards and does not raise any safety and effectiveness issues.

1. AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

The Digital Thermometer complies with to applicable ANSI/AAMI ES60601-1 requirements including general requirements, protection against electrical hazards, protection against mechanical hazards, protection against excessive temperatures, hazardous situations and fault conditions, and constructions.

2. AAMI / ANSI/ IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

   The Digital Thermometer complies with applicable ANSI/AAMI/IEC 60601-1-2 requirements including radiated emission test, electrostatic discharge immunity test, radiated RF electromagnetic field immunity test, and power frequency magnetic field immunity test.

3. ASTM E1112-00 (Reapproved 2011), Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

   The Digital Thermometer complies applicable ASTM E1112 requirements including displayed temperature range, maximum permissible laboratory error, ambient conditions for operation and storage, human interface and mechanical test.

4. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

   The Digital Thermometer complies applicable the guidance requirements including level of concern, software description, software requirements specification, architecture design chart, software design specification, verification and validation documentation.

5. Biocompatibility:
   AAMI / ANSI / ISO 10993-1:2009(R)2013 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process;
   AAMI / ANSI / ISO 10993-5:2009(R)2014 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity and

AAMI / ANSI / ISO 10993-10:2010(R)2014 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

The Digital Thermometer complies applicable biocompatibility requirements and the device met the endpoints for cytotoxicity, sensitization & irritation-negligible

The Digital Thermometer is verified and validated by evaluating safety, EMC, device-specific standard ASTM E1112-00, software validation and biocompatibility testing without raising any safety and effectiveness issues.

9. Conclusions

The Digital Thermometer has the similar intended use, materials, technological characteristics and the same fundamental scientific technology with the predicate device. Moreover, both devices comply with same performance standards. All information described above can demonstrate the subject device is substantial equivalent to the predicate device.