Tab #2 510(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: K170769

1. Date of Preparation: 07/24/2017

2. Sponsor Identification

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4. Identification of Proposed Device

Trade Name: Wireless Thermometer, Model(s): ECH-b1-L, ECH-b1-M, and ECH-b1-S

Common Name: Clinical electronic thermometer
Model(s): ECH-b1-L, ECH-b1-M, ECH-b1-S

Regulatory Information

Classification Name: Clinical electronic thermometer
Classification: Class II
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Review Panel: General Hospital

5. Intended Use Statement:
The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. The system is intended for armpit temperature monitoring for persons with all ages.
The products can be used in hospital and at home.

6. Device Description

The MCU chip in the wireless electronic thermometer collects the voltage value of the NTC thermal resistor, a thermo-sensitivity resistance, whose resistance will change according to temperature. After collecting and filtering algorithm, a resistance value data is obtained. After that, the Bluetooth chip performs a table lookup operation to find the Celsius temperature value corresponding to the resistance value. The temperature data is transmitted through the Bluetooth transmission to the compatible smart phone, in order to achieve the function of temperature measurement.

The wireless thermometer is composed of a Patch and a Mobile App.

- Patch: One side of Patch is medical adhesive which is used to fix the patch on the armpit of patients. The other side is foam. There is a circuit board inside the patch. The patch is used for detecting of human body temperature and then transferred to Mobile App for display and further management. There is no display function on the patch, except for a indicator to indicating power on/off status.

  Patches are single use only, and available in different configuration. The models ECH-b1-S, ECH-b1-M and ECH-b1-L all share the same design principles, materials, mechanism of actions. However they are different in size and intended patient.

- Mobile APP: The APP is intended for display and management of obtained human body temperature data.

The mobile APP is intended to be run on compatible smart phones with iOS operating system or Android operating system, including:

- iPhone 5, iPhone 5s, iphone 5C, iPhone 6, iPhone 6 Plus, iPhone 6s, iPhone 6s Plus, Iphone SE, iPhone 7, iPhone 7 Plus smart phone run on IOS 7.1 or advanced operation system or
- Nexus 5, Sumsang Galaxy S6, Huawei Mate 8 smart phone run on Android 4.4 or advanced operation system.

Its function includes:

- Patient management;
- Communication with Patch;
- Simultaneous display of temperature;
- Indication of low battery content of patch.

There is no alarming and interpretation feature.

7. Identification of Predicate Device(s)

510(k) Number: K143267
Product Name: TempTraq, Model TT-100

8. 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 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 60601-1-2:2014, 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.
- IEC 60601-1-11:2010 Medical electrical equipment- Part 1-11:General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical system used in the home healthcare environment

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device	Remark
Product Code	FLL	FLL	Similar
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	Similar
Class	Clinical electronic thermometers	Clinical electronic thermometers	Similar
Intended Use	The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is intended for armpit temperature monitoring for persons with all ages The products can be used in hospital and at home.	The wireless thermometer, model TT-100, is a battery-operated electronic device with intended use of measuring human body temperature precisely. This device is a single-use and intended for armpit temperature measurement of persons of all age.	Similar
Measurement Site	Under the armpit	Under the armpit	Similar
Features	Compatible with iOS or Android Mobile Device via Bluetooth connection	Compatible with iOS or Android Mobile Device via wireless connection	Similar
	Display in mobile application, no display on device	Display in mobile application, no display on device	Similar
Component	Temperature Sensitive Sensor	Temperature Sensitive Sensor	Similar
	Circuit Board	Circuit Board	Similar
	No Cable	No cable	Similar
	Battery (button cell)	Battery(button cell)	Similar
Working voltage	3.0Vdc	3.0 Vdc	Similar
Measurement range	25.0~45.0 ℃	30~42.4 ℃	Similar

Accuracy	±0.2 ℃ for 25-45 ℃,		±0.1 ℃ for 30-42.4 ℃,	Similar
Signal transmission	Bluetooth Version 4.0		Bluetooth Version 4.0	Similar
Receiver	IOS 7.1 or later/ Android 4.4 or later based smart phones with Bluetooth® 4.0interface.		IOS 7.1 through 8.1 or Android operating 4.3 through 4.4 operating system supportable smart phones	Similar
Unit	℃ or ℉		°C or °F	Similar
Biocompatibility	Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-5 and ISO 10993-10	Similar
	Sensitization	No sensitization		
	Irritation	Negligible		
Electrical Safety	Complied with IEC 60601-1		Complied with IEC 60601-1	Similar
EMC	Complied with IEC 60601-1-2		Complied with IEC 60601-1-2	Similar

The intended use, measurement range and accuracy of proposed device and predicate device are different. Intended use of the proposed device and predicate device are the same. The difference is only expression difference. The measurement range and accuracy of proposed device is different from that of the predicated device, but both the proposed device and predicated device comply with IEC 80601-2-56. Therefore, these differences will not affect the substantially equivalency concerning safety and effectiveness.

11. 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