510(k) Summary

K173730

I. SUBMITTER

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II. DEVICE

Trade Name	Kinsa QuickCare Thermometer
Model Name	KSA-110
Common or Usual Name:	Oral, rectal and axillary digital electronic thermometer
Classification Number:	21 CFR 880.2910
Classification Name:	Clinical electronic thermometer
Product Code:	FLL
Product Class:	II
Classification Panel:	General Hospital

III. PREDICATE DEVICE

Predicate device:

K Number	K043110
Trade Name	Vick, Vicks
Current 510(k) Holder	Kaz USA Inc., a Helen of Troy Company
Device Name:	Microlife Instant Digital Thermometer, Model MT18I1
Classification Number:	21 CFR 880.2910
Classification Name:	Clinical electronic thermometer
Product Code:	FLL

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

Reference device: K152975 VDT985US Vicks SmartTemp Thermometer from KAZ USA, Inc.

The VDT985US thermometer provides an example of a cleared device that communicates wireless to a smart phone application as the receiver in support of the BLE wireless technological characteristic available in the proposed Kinsa QuickCare Thermometer.

IV. DEVICE DESCRIPTION

The Kinsa QuickCare Thermometer is a battery powered, thermistor based predictive Bluetooth low energy (BLE) enabled thermometer used for the measurement and monitoring of human body temperature. Body temperature can be measured with the Kinsa QuickCare Thermometer orally, axillary (under the arm), and rectally. The thermometer is reusable for clinical and/or home use on people of all ages with adult supervision. The device can be used with as a stand-alone device or in conjunction with the Kinsa App on a compatible BLE enabled smartphone.

V. INDICATIONS FOR USE

The Kinsa QuickCare Thermometer is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm. The device is for the adult and pediatric population.

The proposed device has the identical intended use as the predicate device and both are indicated for Over-the-Counter use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technology of the Kinsa QuickCare Thermometer is identical to the predicate device in terms of its principle of operation, thermistor, prediction algorithm, probe tip design and materials. The industrial design is similar to the predicate except for the outer shell form. The Bluetooth feature is an additional feature similar to the reference device.

Element of comparison	**Subject Device Kinsa QuickCare Thermometer**	**Predicate Device Microlife MT18I1 Instant Digital Thermometer (V966 Vicks) K043110**	**Analysis**
Thermometer type	Predictive digital	Predictive digital	Same
Fundamental technology & Operating principle	Utilizes an NTC thermistor located in the probe tip to sense human body temperature when placed in the desired measuring site (mouth, underarm, and rectum). The resulting change in resistance is	Based on conduction of heat to a thermistor based sensor and use of predictive algorithms to estimate the body temperature	Same

	sensed and monitored in order to through use of predictive algorithms estimate human body temperature		
Operation	Handheld device containing user facing button, sensor head, microcontroller, display	Handheld device containing an On/Off switch, sensor head, microcontroller and display	Similar
Sensor	Thermistor based	Thermistor based	Same
Signal processing and display	- Internal firmware and local LCD display - Also able to transfer transmit data to an auxiliary device for secondary display	Internal firmware and local LCD display	Same primary display. The secondary display option in the subject device achieved via Bluetooth wireless communication to a smart device is not a new technology and is present in many medical devices including thermometers. Kinsa has included the K152975 thermometer as an example of such a device. This difference does not raise new questions of safety and effectiveness and the subject device remains substantially equivalent to the predicate device.
Wireless Interface	Bluetooth Low Energy (BLE)	None	Different technology included in the subject device. Same rationale applies as above.
Power requirements	Battery powered CR2032 (3V)	Battery powered	Same
Battery duration	More than 600 measurements or approximately 2 years if used every day.	More than 200 hours of continuous operation or 2 years if used 10 min per day	Similar, battery performance tested supports the battery duration of the subject device

Materials	Biocompatible metals and resins	Biocompatible metals and resins	Same
Scale	°F / °C	°F / °C	Same
Measurement locations	Oral, Axillary and Rectal	Oral, Axillary and Rectal	Same
Measurement Range	32°C to 42.8°C (89.6 to 109.2°F)	32 °C to 42.9 °C (89.6 °F to 109.2 °F)	Same
Operating Environment	15 to 35°C 15-85% relative humidity, non-condensing	Unknown	Tested and complies with IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-56
Storage Environment	-25 to 70 °C Up to 90% Relative humidity, non-condensing, up to 50 hPa	Unknown	Tested and complies with IEC 60601-1 and IEC 60601-1-11
Accuracy	± 0.2°C within measurement range of 32 to 42.8°C (89.6 to 109.2°F)	± 0.2 °F (± 0.1 °C) within measurement range 96 to 107°F	Difference in specification but subject device complies with device specific FDA recognized thermometer standard ISO 80601-2-56 and in comparison, evaluation with the predicate device the performance is the same. Therefore, this is not considered a difference since the performance is the same as the predicate and the difference in the specification does not raise different questions of safety and effectiveness. The subject substantially equivalent to the predicate in laboratory accuracy.
Response Time	8 sec nominally	±8 sec	Same
Resolution of Display	0.1 °C / 0.1°F	0.1 °C / 0.1°F	Same
Performance	Meets ISO 80601-2-56	Meets ASTM E1112	Similar, both device specific FDA recognized thermometer standard have similar

			requirements and acceptance criteria. Performance comparison with the predicate device demonstrates laboratory accuracy of the subject device is the same as the predicate device over the same temperature range.
Biocompatibility	Meets ISO 10993-1	Meets ISO 10993-1	Same
Electrical Safety	Meets ES 60601-1	Meets IEC 60601-1	Same
Electromagnetic Disturbances	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

VII. PERFORMANCE DATA

Non-clinical

Non-clinical performance reports were provided to document verification and validation activities intended to demonstrate substantial equivalence of the subject device to the predicate device:

1. Design Verification results confirmed the device meets the product requirements set by Kinsa and the performance standard requirements of ISO 80601-2-56:2009, Medical Electrical Equipment – Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
2. Software Verification and Validation results confirmed the firmware and software units meet the software requirements specifications and the system performs as intended. Software documentation is provided in accordance with the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).
3. Labeling verification per the recommendations within the FDA "Guidance on the Content of Premarket Notification [510(k)] Submission for Clinical Electronic Thermometers.
4. All skin contacting materials have been tested successfully for biocompatibility: cytotoxicity in accordance with AAMI/ANSI/ISO 10993-5:2009 /(R)2014, Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity, as well as irritation and sensitization in accordance with ISO 10993-10:2010, Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization.
5. Electrical and Mechanical Safety as well as essential performance was confirmed through compliance testing to AAMI/ANSI ES 60601-1:2005/(R)2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-11:2015, Medical Electrical Equipment Part 1-11: Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.

6. Electromagnetic Compatibility was confirmed through compliance testing to IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: Electromagnetic Disturbances – Requirements and Tests.
7. Cybersecurity management has been addressed in accordance with the recommendations in the relevant FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)"

Clinical

There is no difference in the intended use, operating principle, and technology, in comparison to the predicate device, thus clinical testing in accordance with ISO 80601-2-56 was deemed unnecessary. The Bluetooth feature, similar to the reference predicate, is an additional feature solely for wireless transmission of data and does not affect measurements, calculations or local display of measurements on the LCD displays of the thermometer.

VII. CONCLUSIONS

Based on the testing and compliance with acceptable voluntary FDA recognized consensus standards, we believe that the KINSA QuickCare Thermometer is substantially equivalent to the predicate Microlife MT18I1 Instant Digital Thermometer and is as safe and as effective as this predicate.