DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 23, 2016

KAZ USA Inc., A Helen Of Troy Company
Mr. Raj Kasbekar
Global Vice President, Regulatory Affairs
250 Turnpike Road
Southborough, Massachusetts 01772

Re: K152975
Trade/Device Name: VDT985US Vicks® SmartTemp™ Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 8, 2016
Received: February 10, 2016

Dear Mr. Kasbekar:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152975

Device Name

VDT985US Vicks® SmartTemp™ Thermometer

Indications for Use *(Describe)*

The VDT985US Vicks® SmartTemp™ Thermometer is indicated for the intermittent measurement and monitoring of human body temperature orally, rectally or under the arm. It can be used on people of all ages except preterm babies or very small (for gestational age). This thermometer is intended to be used with Apple and Android mobile devices. It is intended for household use only.

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.

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510(k) Summary K152975

1. **Preparation Date:**

March 15, 2016

2. **Submitted By:**

KAZ USA, Inc., a Helen of Troy Company
400 Donald Lynch Boulevard, Suite 300
Marlborough, MA 01752

Primary Contact Person/Prepared by:

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3. **Device Identification:**

3.1 **Trade Name**

VDT985US Vicks® SmartTemp™ Thermometer

3.2 **Common Name**

Oral, rectal and axillary digital electronic thermometer

3.3 **Classification Name**

21CFR 880.2910: Thermometer, Clinical, Electronic
Class II, Product code: FLL

4. **Predicate Device:**

Predicate	Manufacturer	510(k) Number
MT18I1 (V966) Instant Digital Electronic Thermometer	Microlife Corporation	K043110
WT701 Wireless Thermometer	Raiing Medical Company	K132761

5. **Device Description:**

Overview: The VDT985US Vicks® SmartTemp™ Thermometer is a general purpose thermometer. The thermometer is intended for oral, axillary temperature measurements of the human body. The main user interface for the thermometer is a smartphone or other Bluetooth smart device on which the Kaz SmartTemp app is installed. The thermometer communicates with the user's device through a Bluetooth smart connection.

Bluetooth Smart Radio and MCU: The Bluetooth Radio is part of a system on chip (SoC) by Texas Instruments. The CC2541 is comprised of a Bluetooth Smart radio and 8051 MCU. The unit defaults to sleep mode, in which the radio is off and the MCU is in time keeping low current mode. The thermometer measures temperature through a thermistor located in the tip of the device, which is measured using a resistor divider sampled by an onboard Analog to Digital Converter (ADC). When the thermometer is activated via a momentary contact switch, the unit enters normal operation mode. In normal operation mode, the radio is active and connects with the user's SmartTemp app on their device. The temperature measurement is then communicated to the SmartTemp app.

6. **Indications for Use**:

The VDT985US Vicks® SmartTemp™ Thermometer is indicated for the intermittent measurement and monitoring of human body temperature orally, rectally or under the arm. It can be used on people of all ages except preterm babies or very small (for gestational age). This thermometer is intended to be used with Apple and Android mobile devices. It is intended for household use only.

7. **Validation Results:**

Clinical Study to show substantial equivalence: A comparison study and clinical repeatability testing was performed on the following four age groups: 0-12 months, 12 months- <5 years, 5 years- <18 years, and 18 years and older in accordance with ASTM E1112-00(2006) and Clinical section (Appendix A) of ASTM E1965 to compare the VDT985US Vicks® SmartTemp™ Thermometer (test thermometer) with the predicate device, the Vicks V966 Thermometer (K043110). The reference or the gold standard used was the Welch Allyn SureTemp® Plus in the monitoring mode (K030580). This clinical comparison study demonstrated that the VDT985US Vicks® SmartTemp™ Thermometer is as good as (non-inferior or substantially equivalent to) the previously approved Vicks V966 Thermometer (K043110) in all age groups with respect to the bias and standard deviation in comparison to the reference Welch Allyn SureTemp® Plus in the monitoring mode (K030580). The temperatures obtained with the test Thermometer were highly related when compared to the predicate device. The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM E1112 standard were within clinical acceptability limits in accordance with the protocol (bias less than predicate device when compared to reference). The clinical repeatability of the test thermometer was statistically and clinically acceptable (less than 0.3 °C or 0.58°F).

8. **Similarities/Differences of the proposed candidate device when compared to the predicate:**

8.1 Intended Use

The predicate device, the Microlife MT18I1 Thermometer (K043110) is also intended for the intermittent determination of the human's body temperature for people of all ages. The intended use and indications for use of the MT18I1 Thermometer (predicate) and the VDT985US Vicks® SmartTemp™ Thermometer are similar. In addition, the WT1701

Raiing Company Wireless Thermometer (K132761) uses the wireless feature that is similar to the VDT985US Vicks® SmartTemp™ Thermometer Bluetooth wireless feature. The predicate device MT18I1 as well as the KAZ VDT985US Vicks® SmartTemp™ Thermometer uses the oral, axillary and rectal as the measurement site.

8.2 Materials

Materials used in the manufacture of the VDT985US Vicks® SmartTemp™ Thermometer are similar (derived from similar resins) to the predicate device. All skin contacting materials used in the new thermometer have been tested successfully for biocompatibility (cytotoxicity in accordance with ISO 10993-5 as well as irritation and sensitization in accordance with ISO 10993-10) and FDA Blue book memo G 95-1 for both thermometers.

8.3 Design

The industrial design of the VDT985US Vicks® SmartTemp™ Thermometer is similar to the predicate device, the Microlife MT18I1 Thermometer (K043110), except for a new outer shell.

8.4 Operational Principles

The VDT985US Vicks® SmartTemp™ Thermometer is a handheld device, containing an On/Off switch, sensor area, microcontroller to control the device and take measurements. The operating principle is based on conduction of heat to a thermistor based sensor and use of predictive algorithms to estimate the body temperature.

8.5 Technology

The technology of the VDT985US Vicks® SmartTemp™ Thermometer is identical to the predicate device MT18I1. The bluetooth feature is an additional feature similar to the predicate WT701.

8.6 Comparison Table between Subject Device and Predicates

ELEMENT OF COMPARISON	**VDT985US Vicks® SmartTemp™ Thermometer**	**Predicate Device: MT18I1**	**Predicate Device: WT701**
Manufacturer	KAZ USA, Inc.	Microlife: MT18I1	Raiing Medical Company: WT701
Classification	21CFR 880.2910	21CFR 880.2910	21CFR 880.2910
Product Code	FLL	FLL	FLL
Class	II	II	II
Thermometer type	Predictive Digital	Predictive Digital	Predictive Digital

Intended use	The VDT985US Vicks® SmartTemp™ Thermometer is indicated for the intermittent measurement and monitoring of human body temperature orally, rectally or under the arm. It can be used on people of all ages except preterm babies or very small (for gestational age). This thermometer is intended to be used with Apple and Android mobile devices. It is intended for household use only.	Microlife MT18I1 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 WT701 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 reusable and intended for armpit temperature monitoring for persons over two years old.
Operation	Handheld device containing an On/Off switch, sensor head, microcontroller, and display on the smartphone.	Handheld device containing an On/Off switch, sensor head, microcontroller, and display	Handheld device containing an On/Off switch, sensor head, microcontroller, and wireless capability
Sensor	Thermistor based	Thermistor based	Thermistor based
Signal processing and display	Internal software and display on smartphone	MT18I1: Internal software and display	MT18I1: Internal software and display as well as wireless display
Power requirements	Battery powered (3V)	Battery powered (1.55V)	Battery powered (3V)
Battery Duration	More than 100 measurements or approximately 2 years if used every week	More than 200 hours of continuous operation or 2 years if used 10 min per day	Similar

Materials	Impact Resistant Casing and Sealed Sensor. Biocompatible metals and resins.	Impact Resistant Casing and Sealed Sensor. Biocompatible metals and resins.	Impact Resistant Casing and Sealed Sensor. Biocompatible metals and resins.
Scale	Degree F /Degree C	same	same
Measurement locations	Oral, Axillary and Rectal	Oral, Axillary and Rectal	Oral, Axillary and Rectal
Measurement range	89.6° F to 109.2° F (32°C to 42.9 °C)	89.6° F to 109.2° F (32°C to 42.9 °C)	25-45 °C
Operation environment	50.0° F to 104.0° F (10°C to 40 °C) Humidity: 15 -95% (non condensing)	Similar	Similar

Storage environment	-13° F to 131° F (-25°C to 55 °C) Humidity: 15 -95% (non condensing)	Similar	Similar
Accuracy	±0.2° F (± 0.1 ° C) within measurement range 95.9-107.6° F and ± 0.4° F outside this range	±0.2°F(±0.1 ° C) within measurement range 96-107° F	±0.05 ° C (35 to 38.5 °C) ±0.1 ° C (25 to 35.99° C and 38.51 -45° C)
Operating environment	Complies with ASTM E1112:2006 Standard	Complies with ASTM E1112:2006 Standard	Complies with ASTM E1112:2006 Standard
Clinical Accuracy: clinical bias with its uncertainty and repeatability	Per ASTM E 1965-09 Clinical Requirements	Similar	Similar
Limit of agreement (clinical)	Per ASTM E 1965-09 Clinical Requirements	Similar	not known
Response time	6 sec (up to 20 sec for axillary/rectal)	Similar	Similar
ASTM E1112-2006 Standard for intermittent determination of patient temperature	Complies with ASTM E1112-2006 Standard	Complies with ASTM E1112-2006 Standard	Complies with ASTM E1112-2006 Standard

IEC/ISO/EN 60601-1-2 Medical Electrical Equipment- Part 1 General Requirements for Safety, Electromagnetic Compatibility- Requirements and Tests	Complies with IEC 60601-1-2:2006 Standard	Complies with IEC 60601-1-2:2006 Standard	Complies IEC 60601-1-2:2006 Standard
IEC/ISO/EN 60601-1 Medical Electrical Equipment- Part 1 General Requirements for Electrical Safety, Requirements and Tests	Complies with IEC 60601-1: 2005 Standard	Complies with IEC 60601-1: 2005Standard	Complies with IEC 60601-1 :2005 Standard

Biocompatibility- ISO 10993-1	Complies with ISO 10993-5 standard for cytotoxicity, 10993- 10 standard for irritation as well as sensitization on biocompatibility for surface contact less than 24 hours and FDA memo G95-1 through tests done in a certified laboratory	Complies with ISO 10993-5 standard for cytotoxicity,10993-10 standard for irritation as well as sensitization on bio-compatibility for surface contact less than 24 hours	Not known

9. **Conclusion:**

Based on the testing and compliance with acceptable voluntary standards, we believe that the VDT985US Vicks® SmartTemp™ Thermometer (K152975) is substantially equivalent to its predicate devices cited above and is as safe and as effective as these predicate devices.