August 14, 2018

Kaz USA, Inc., A Helen of Troy Company
Matt Baun
Associate Director of Clinical & Regulatory Affairs
400 Donald Lynch Boulevard, Suite 300
Marlborough, MA 01752

Re: K180131
Trade/Device Name: Vicks RapidRead Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 9, 2018
Received: July 9, 2018

Dear Matt Baun:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180131

Device Name

Vicks® VDT972 RapidRead™ Digital Thermometer

Indications for Use *(Describe)*

The Vicks® VDT972 RapidRead™ Digital Thermometer is a handheld, battery-powered, predictive, digital stick thermometer intended for the intermittent determination of human body temperature orally, rectally, or under the arm, in a home-use environment for people of all ages (infants, children, and adults). It is intended to be used with a single-use, disposable probe cover for all measurements.

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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Section 5: 510(k) Summary K180131

I. SUBMITTER

KAZ USA, Inc., A Helen of Troy Company
400 Donald Lynch Blvd., Suite 300
Marlborough, MA 01752
Phone: (508) 490-7240
Fax: (508) 251-1048
Contact Person: Matt J. Baun, Associate Director of Clinical & Regulatory Affairs
Date Prepared: 8-November-2017

II. DEVICE

Name of Device: Vicks® VDT972 RapidRead™ Digital Thermometer
Common or Usual Name: Axillary / Oral / Rectal, Predictive Digital Thermometer
Classification Name: Thermometer, Clinical, Electronic (21CFR 880.2910)
Regulatory Class: II
Product Code: FLL

III. PREDICATE DEVICE(S)

- V966 Vicks® ComfortFlex® Digital Thermometer (Microlife Instant Digital Thermometer, Model MT18L1) - 510(k) # K043110
- Vicks® VDT985 SmartTemp™ Wireless Thermometer - 510(k) # K152975

IV. DEVICE DESCRIPTION

The Vicks® VDT972 RapidRead™ Digital Thermometer is a predictive, thermistor-based, stick thermometer capable of measuring oral, axillary, or rectal temperature in 2 to 8 seconds. It is equipped with a site selection button that requires the operator to select the desired measurement site before taking a temperature. For each measurement, it must be used with a commercially-available, single-use, disposable probe cover.

The Vicks® VDT972 RapidRead™ Digital Thermometer is a contact thermometer, using a negative temperature coefficient (NTC) thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes. This change in resistance is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user.

The Vicks® VDT972 RapidRead™ Digital Thermometer does not use a clinical offset algorithm. clinical offset algorithms are typically used to perform a measurement on one physiological site (i.e. the forehead, temple, or ear) and represent what the equivalent measurement would be at a different physiological site (i.e. oral), had the measurement been performed at that site instead. Typically, these formulas account for ambient temperature, at a minimum, in calculating the appropriate offset. Because the Vicks® VDT972 RapidRead™ Digital Thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via the use of a clinical offset.

V. INDICATIONS FOR USE

The Vicks® VDT972 RapidRead™ Digital Thermometer is a handheld, battery-powered, predictive, digital stick thermometer intended for the intermittent determination of human body temperature orally, rectally, or under the arm, in a home-use environment for people of all ages (infants, children, and adults). It is intended to be used with a single-use, disposable probe cover for all measurements.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE(S)

Substantial Equivalence Comparison Table - Vicks® V966 ComfortFlex® Digital Thermometer

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® V966 ComfortFlex® Digital Thermometer	Comparison
Manufacturer (Legal)	Kaz USA, Inc., a Helen of Troy Company	Kaz USA, Inc., a Helen of Troy Company	
Contract Manufacturer	Microlife Corporation	Microlife Corporation	
Thermometer Type	Axillary / Oral / Rectal, Predictive Digital Thermometer	Axillary / Oral / Rectal, Predictive Digital Thermometer	Substantially Equivalent
Models	Vicks® VDT972 RapidRead™ Digital Thermometer	V966 Vicks® ComfortfFlex® Digital Thermometer (Microlife Instant Digital Thermometer, Model MT18L1)	
510(k) Number	K180131	K043110	
Intended Use	The Vicks® VDT972 RapidRead™ Digital Thermometer is a handheld, battery-powered, predictive, digital stick thermometer intended for the intermittent determination of human body temperature orally, rectally, or under the arm, in a home-use environment for people of all ages (infants, children, and adults). It is intended to be used with a single-use, disposable probe cover for all measurements.	V966 Vicks® ComfortFlex® Digital Thermometer (Microlife Instant Digital Thermometer, Model MT18L1) is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm. The device is for the adult & pediatric population.	Substantially Equivalent
User Population	Infants, children, and adults	Adult and pediatric	Substantially Equivalent
Labeling	Instructions for use, package / box, and rating label	Instructions for use, package / box, and rating label	Substantially Equivalent
Components	On / Off Button, Site Selection Button, sensor head, protective cover, microcontroller, & LCD	On / Off Button, sensor head, protective cover, microcontroller, & LCD	Substantially Equivalent
Sensor	Thermistor	Thermistor	Substantially Equivalent
Principles of Operation	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	Substantially Equivalent
Measurement Range	34.0°C to 43.0°C (93.2°F to 109.4°F)	32.0°C to 42.9°C (89.6°F to 109.2°F)	Substantially Equivalent

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® V966 ComfortFlex® Digital Thermometer	Comparison
Accuracy	± 0.1°C / 0.2°F within measurement range (34.0°C to 43.0°C / 93.2°F to 109.4°F) at room temperature of 71°F	± 0.1°C / 0.2°F within measurement range (35.6°C to 41.7°C / (96.0°F to 107.0°F) at room temperature of 71°F	Substantially Equivalent
Resolution of Display	0.1°C / 0.1°F	0.1°C / 0.1°F	Substantially Equivalent
Response Time	2 to 8 seconds	8 to 15 seconds	Substantially Equivalent
MCU	The Sonix SN8F5907 is an 8-bit architecture microcontroller which is compatible with MCS-51 instruction set. It includes an enhanced 8051 microcontroller, up to 32 MHz flexible CPU frequency, hardware multiplication / division Unit, 256 bytes internal RAM (IRAM), 2 KB external RAM (XRAM), 64 KB non-volatile flash memory (IROM), in-system program support, 10 interrupt sources with priority control, 2 external interrupts: INT0, INT1, 3 set 16-bit timer/counter with auto reload, PWM output function, 1 set 8-bit base timer for RTC, 1 set buzzer function output pin, one comparator for low battery detect 2.2V~3.6V (0.2V/step), 1 set charge pump regulator (AVDDR and ACM), 1 set programmable gain instrument amplifier (Gain:1x~128x), 24-bit Delta Sigma ADC with 9 external channels and 4 internal channels, 1 set operational amplifier, C-type LCD driver up to 252 dot (4x44 or 6x42 dots), programmable watchdog and software reset, SPI, UART, I2C interface with SMBus support, on-chip debug support (single-wire debug interface), wide supply voltage (1.8V to 5.5V), wide working temperature (-40°C to 85°C).	The Holtek HT47C20 is an 8-bit high performance RISC-like microcontroller. It includes a 2.4V~3.6V operating voltage, eight bidirectional I/O lines, four input lines, one interrupt input, one 16-bit programmable timer / event counter with PFD (programmable frequency divider) function, on-chip crystal and RC oscillator for system clock, one 32.768kHz crystal oscillator for real time clock, Watchdog Timer, 2K16 program memory ROM, 648 data memory RAM, one Real Time Clock (RTC), one 8-bit prescaler for RTC, one buzzer output, HALT function and wake-up feature to reduce power consumption, LCD bias C type, one LCD driver with 203 or 194 segments, one 38kHz or 40kHz IR carrier output (455kHz or 480kHz system clock only), two channels RC type A/D converter, four-level subroutine nesting, bit manipulation instruction, 16-bit table read instruction, up to 8.3s instruction cycle with 480kHz system clock, all instructions in one or two machine cycles, 63 powerful instructions, 64-pin QFP package G	Substantially Equivalent
Signal Output and Display	LCD, Buzzer	LCD, Buzzer	Substantially Equivalent
Operating Environment	15.0°C to 40.0°C / 59.0°F to 104.0°F; ≤ 95% Relative Humidity	10°C to 40°C / 50°F to 104°F; 15-95% Relative Humidity	Substantially Equivalent
Storage Environment	-25.0°C to 60.0°C / -13.0°F to 140.0°F; ≤ 95% Relative Humidity	-25.0°C to 60.0°C / -13.0°F to 140.0°F; 15-95% Relative Humidity	Substantially Equivalent
Power Supply	One (1), 3V, CR2032 battery	One (1), 3V, CR1225 battery	Substantially Equivalent
Battery Life	More than 400 measurements or approximately 2 years if used every other day.	More than 300 measurements or approximately 2 years if used every other day.	Substantially Equivalent

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® V966 ComfortFlex® Digital Thermometer	Comparison
Materials	User contacting materials include ABS (sensor head, battery door and On / Off Button), TPR (probe and Site Selection Button), PMMA (LCD lens and protective cover), and stainless steel (sensor tip)	User contacting materials include ABS (sensor head and battery door), TPR (probe, LCD lens casing, On / Off Button, and sensor head seam strip), PMMA (LCD lens and protective cover), and stainless steel (sensor tip)	Substantially Equivalent
Performance	Meets ASTM E1112-00:2011 and ISO 80601-2-56:2017	Meets ASTM E1112	Substantially Equivalent
Biocompatibility	Meets ISO 10993-1:2009, 10993-5:2009, 10993-10:2010, and FDA Guidance Document, "Use of International Standard ISO 10993-1" – June 16, 2016	Meets ISO 10993-1, 10993-5, and 10993-10, and FDA Bluebook memo G95-1	Substantially Equivalent
Safety	Meets EN 60601-1:2014	Meets IEC 60601-1	Substantially Equivalent
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2	Substantially Equivalent

Substantial Equivalence Comparison Table - Vicks® VDT985 SmartTemp™ Wireless Thermometer

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® VDT985 SmartTemp™ Wireless Thermometer	Comparison
Manufacturer (Legal)	Kaz USA, Inc., a Helen of Troy Company	Kaz USA, Inc., a Helen of Troy Company	
Contract Manufacturer	Microlife Corporation	Microlife Corporation	
Thermometer Type	Axillary / Oral / Rectal, Predictive Digital Thermometer	Axillary / Oral / Rectal, Predictive Digital Thermometer	Substantially Equivalent
Models	Vicks® VDT972 RapidRead™ Digital Thermometer	Vicks® VDT985 SmartTemp™ Wireless Thermometer	
510(k) Number	K180131	K152975	
Intended Use	The Vicks® VDT972 RapidRead™ Digital Thermometer is a handheld, battery-powered, predictive, digital stick thermometer intended for the intermittent determination of human body temperature orally, rectally, or under the arm, in a home-use environment for people of all ages (infants, children, and adults). It is intended to be used with a single-use, disposable probe cover for all measurements.	Vicks® VDT985 SmartTemp™ Wireless 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.	Substantially Equivalent
User Population	Infants, children, and adults	People of all ages except preterm babies or very small (for gestational age)	Substantially Equivalent
Labeling	Instructions for use, package / box, and rating label	Instructions for use, package / box, and rating label	Substantially Equivalent
Components	On / Off Button, Site Selection Button, sensor head, protective cover, microcontroller, & LCD	On / Off Button, sensor head, microcontroller, LED status indicator, & protective cover	Substantially Equivalent

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® VDT985 SmartTemp™ Wireless Thermometer	Comparison
Sensor	Thermistor	Thermistor	Substantially Equivalent
Principles of Operation	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	The thermometer uses a negative temperature coefficient thermistor embedded in a measurement tip that is in contact with the measurement site. As the thermistor changes temperature, the resistance of the thermistor also changes, which is measured by the thermometer and converted to a measurement of the temperature of the tip of the thermometer. This temperature, following the use of the predictive algorithm, is then displayed to the end user on their smartphone via Bluetooth communication using the Vicks® SmartTemp™ Thermometer app. Because the thermometer displays the measurement for the physiological site at which it is used, it does not need to convert this temperature via clinical offset.	Substantially Equivalent
Measurement Range	34.0°C to 43.0°C (93.2°F to 109.4°F)	32.0°C to 42.9°C (89.6°F to 109.2°F)	Substantially Equivalent
Accuracy	± 0.1°C / 0.2°F within measurement range (34.0°C to 43.0°C / 93.2°F to 109.4°F) at room temperature of 71°F	± 0.1°C / 0.2°F within measurement range (35.5°C to 42.0°C / (95.9°F to 107.6°F) at room temperature of 71°F	Substantially Equivalent
Resolution of Display	0.1°C / 0.1°F	0.1°C / 0.1°F	Substantially Equivalent
Response Time	2 to 8 seconds	8 to 15 seconds	Substantially Equivalent
Signal Output and Display	LCD, Buzzer	LCD, Buzzer	Substantially Equivalent
Operating Environment	15.0°C to 40.0°C / 59.0°F to 104.0°F; ≤ 95% Relative Humidity	10°C to 40°C / 50°F to 104°F; 15-95% Relative Humidity	Substantially Equivalent
Storage Environment	-25.0°C to 60.0°C / -13.0°F to 140.0°F; ≤ 95% Relative Humidity	-25.0°C to 55.0°C / -13.0°F to 131.0°F; 15-95% Relative Humidity	Substantially Equivalent
Power Supply	One (1), 3V, CR2032 battery	One (1), 3V, CR2032 battery	Substantially Equivalent
Battery Life	More than 400 measurements or approximately 2 years if used every other day.	More than 100 measurements or approximately 2 years if used every week.	Substantially Equivalent

Element of Comparison	Test Device: Vicks® VDT972 RapidRead™ Digital Thermometer	Predicate Device: Vicks® VDT985 SmartTemp™ Wireless Thermometer	Comparison
MCU	The Sonix SN8F5907 is an 8-bit architecture microcontroller which is compatible with MCS-51 instruction set. It includes an enhanced 8051 microcontroller, up to 32 MHz flexible CPU frequency, hardware multiplication / division Unit, 256 bytes internal RAM (IRAM), 2 KB external RAM (XRAM), 64 KB non-volatile flash memory (IROM), in-system program support, 10 interrupt sources with priority control, 2 external interrupts: INT0, INT1, 3 set 16-bit timer/counter with auto reload, PWM output function, 1 set 8-bit base timer for RTC, 1 set buzzer function output pin, one comparator for low battery detect 2.2V~3.6V (0.2V/step), 1 set charge pump regulator (AVDDR and ACM), 1 set programmable gain instrument amplifier (Gain:1x~128x), 24-bit Delta Sigma ADC with 9 external channels and 4 internal channels, 1 set operational amplifier, C-type LCD driver up to 252 dot (4x44 or 6x42 dots), programmable watchdog and software reset, SPI, UART, I2C interface with SMBus support, on-chip debug support (single-wire debug interface), wide supply voltage (1.8V – 5.5V), wide working temperature (-40°C to 85°C).	The Sonix SN8F5909 is an 8-bit architecture microcontroller which is compatible with MCS-51 instruction set. It includes an enhanced 8051 microcontroller, up to 32 MHz flexible CPU frequency, hardware multiplication / division Unit, 256 bytes internal RAM (IRAM), 2 KB external RAM (XRAM), 64 KB non-volatile flash memory (IROM), in-system program support, 10 interrupt sources with priority control, 2 external interrupts: INT0, INT1, 3 set 16-bit timer/counter with auto reload, PWM output function, 1 set 8-bit base timer for RTC, 1 set buzzer function output pin, one comparator for low battery detect 2.2V~3.6V (0.2V/step), 1 set charge pump regulator (AVDDR and ACM), 1 set programmable gain instrument amplifier (Gain:1x~128x), 24-bit Delta Sigma ADC with 9 external channels and 4 internal channels, 1 set operational amplifier, C-type LCD driver up to 252 dot (4x44 or 6x42 dots), programmable watchdog and software reset, SPI, UART, I2C interface with SMBus support, on-chip debug support (single-wire debug interface), wide supply voltage (1.8V – 5.5V), wide working temperature (-40°C to 85°C).	Substantially Equivalent
Materials	User contacting materials include ABS (sensor head, battery door and On / Off Button), TPR (probe and Site Selection Button), PMMA (LCD lens and protective cover), and stainless steel (sensor tip)	User contacting materials include ABS (sensor head and battery door), TPR (probe and On / Off Button), PMMA (face panel and protective cover), and stainless steel (sensor tip)	Substantially Equivalent
Performance	Meets ASTM E1112-00:2011 and ISO 80601-2-56:2017	Meets ASTM E1112 and ISO 80601-2-56	Substantially Equivalent
Biocompatibility	Meets ISO 10993-1:2009, 10993-5:2009, 10993-10:2010, and FDA Guidance Document, “Use of International Standard ISO 10993-1” – June 16, 2016	Meets ISO 10993-1, 10993-5, and 10993-10, and FDA Bluebook memo G95-1	Substantially Equivalent
Safety	Meets EN 60601-1:2014	Meets IEC 60601-1	Substantially Equivalent
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2	Substantially Equivalent

VII. PERFORMANCE DATA

The following performance data for the Vicks® VDT972 RapidRead™ Digital Thermometer are provided in support of the substantial equivalence determination:

BIOCOMPATIBILITY TESTING:

The biocompatibility evaluation for the Vicks® VDT972 RapidRead™ Digital Thermometer was conducted in accordance with International Standards ISO 10993-1:2009, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*, ISO 10993-5:2009, *Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity*, and ISO 10993-10:2010, *Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization*, as recognized by FDA, and per FDA Guidance Document, *Use of International Standard IS10993-1,* "*Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*," issued on June 16, 2016. The test reports for the materials of construction of the thermometer include the following:

- Cytotoxicity
- Irritation
- Sensitization

ELECTROMAGNETIC COMPATIBILITY, BASIC SAFETY, AND ESSENTIAL PERFORMANCE:

An accredited laboratory (Shenzhen Huatongwei International Inspection Company, Ltd.) that was ISO 17025 certified, tested the Vicks® VDT972 RapidRead™ Digital Thermometer for electromagnetic compatibility per IEC 60601-1-2-2014 and for compliance to applicable portions of EN 60601-1:2014. A separate accredited laboratory (Washington Laboratories, Ltd.) that was ISO 17025 certified, tested the Vicks® VDT972 RapidRead™ Digital Thermometer for compliance to applicable portions of IEC 60601-1-11:2015.

Results show the thermometer is in full compliance with these requirements.

SOFTWARE VERIFICATION AND VALIDATION TESTING:

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*," issued on May 11, 2005, and the software lifecycle standard, *IEC 62304:2006 – Medical device software – Software lifecycle processes*. The software for the Vicks® VDT972 RapidRead™ Digital Thermometer was considered as "Moderate Level of Concern", since a malfunction of, or a latent design flaw in, the thermometer could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

FUNCTIONAL PERFORMANCE, RELIABILITY, PACKAGING, AND ENVIRONMENTAL TESTING:

- Performance throughout the environmental range
- Low battery indication and accuracy as a function of supply voltage
- Power consumption, battery voltage, and life
- Audio and visual feedback
- Measurement time test
- Unit life
- Cleaning test, label rubbing, and product art rubbing
- Drop without packaging
- Packaging drop and vibration
- Packaging components check
- Storage
- Water ingress
- Salt spray

CLINICAL STUDY:

Clinical testing of the Vicks® VDT972 RapidRead™ Digital Thermometer included a pivotal study of 165 subjects, 59 (36%) of which were febrile and 74 (44%) of which were male. Substantial equivalence was based in part on the pivotal clinical study.

The investigation was a prospective, multicenter, non-inferiority clinical investigation. In order to test the Vicks® VDT972 RapidRead™ Digital Thermometer for non-inferiority (substantial equivalence) compared to the Vicks® V966 ComfortFlex® Digital Thermometer (510(k) # K043110), both thermometers were compared to the well-established, "Gold Standard" reference device, the Welch Allyn SureTemp® Plus 690 Thermometer (510(k) # K030580).

All readings were taken using calibrated thermometers in accordance with the respective manufacturer's instructions, and all readings were taken using FDA cleared, single-use, disposable probe covers (510(k) # K102508). For all afebrile subjects and febrile subjects greater than or equal to five (5) years of age, one (1) reading was taken with the reference thermometer, the Welch Allyn SureTemp® Plus 690 Thermometer, followed by three (3) consecutive readings with the test thermometer, the Vicks® VDT972 RapidRead™ Digital Thermometer, and three (3) consecutive readings with the predicate thermometer, the Vicks® V966 ComfortFlex® Digital Thermometer, at one-minute intervals. For all febrile subjects less than five (5) years of age, one (1) reading was taken with each the reference thermometer, the test thermometer, and the predicate thermometer, at one-minute intervals. The use order of the test and predicate thermometers for both single measurement and consecutive triplicate measurements was randomized, and the test and predicate devices used were randomized to eliminate any bias.

The following table displays the number of subjects enrolled in the clinical study by age group and temperature measurement site:

Age Group	Axillary Measurement	Rectal Measurement	Oral Measurement	TOTALS
0 to 3 months	13	16	0	**29**
> 3 to 12 months	14	14	0	**28**
> 12 months to 5 years	30	28	0	**58**
> 5 to 18 years	0	0	25	**25**
> 18 years	0	0	25	**25**
TOTALS	**57**	**58**	**50**	**165**

Primary Endpoint:

The Vicks® VDT972 RapidRead™ Digital Thermometer was found to be equivalent to the predicate device, in terms of Clinical Bias, for all age groups combined (0.2°C vs. -0.34°C), each age group individually, and for febrile subjects (0.09°C vs. -0.70°C).

Secondary Endpoint:

The Vicks® VDT972 RapidRead™ Digital Thermometer was found to be equivalent to the predicate device, overall, in terms of Standard Deviation (Limits of Agreement) and Clinical Repeatability for all age groups and febrile subjects. The overall Clinical Bias was < ± 0.20°C (< ± 0.36°F) and the Clinical Repeatability was < ± 0.3°C (< ± 0.54°F).

Effectiveness:

The endpoints for the Vicks® VDT972 RapidRead™ Digital Thermometer pivotal clinical study focused on Clinical Accuracy, which is specified by two characteristics: Clinical Bias, with its Standard Deviation or Limits of Agreement, and Clinical Repeatability. The study results demonstrated that the Vicks® VDT972 RapidRead™ Digital Thermometer was equivalent to the predicate thermometer for Clinical Accuracy for all age groups combines, for each age group individually, and for febrile subjects. Hence,

the study met its endpoints with the required 95% confidence level. Therefore, the effectiveness of the Vicks® VDT972 RapidRead™ Digital Thermometer at accurately measuring human body temperature in a home-use environment is similar to the effectiveness reported for the predicate device.

Safety:
There were no reports of Adverse Events, Serious Adverse Events, or complaints of discomfort while using the Vicks® VDT972 RapidRead™ Digital Thermometer during the pivotal clinical study.

Summary:
Based on the clinical performance as documented in the pivotal clinical study, the Vicks® VDT972 RapidRead™ Digital Thermometer was found to be non-inferior, and therefore, substantially equivalent to the predicate thermometer, having a safety and effectiveness profile that is similar.

VIII. CONCLUSION

The non-clinical data verify the accuracy of the device and the hardware and software verification and validation demonstrate that the Vicks® VDT972 RapidRead™ Digital Thermometer should perform as intended in the specified use conditions. The clinical data validates that the Vicks® VDT972 RapidRead™ Digital Thermometer performs comparably to the predicate device, the V966 Vicks® ComfortFlex® Digital Thermometer (Microlife Instant Digital Thermometer, Model MT18L1), a digital stick thermometer that gives a reading in 8 seconds (510K # K043110), which was cleared for marketing in the US in December 2004. For comparison of user population, it has the same intended use as the predicate device, the Vicks® VDT985 SmartTemp™ Wireless Thermometer, a digital stick thermometer that works with a smartphone app via Bluetooth (510(k) # K152975), which was cleared for marketing in the US in March 2016. Therefore, the Vicks® VDT972 RapidRead™ Digital Thermometer is substantially equivalent to the predicate devices.