April 28, 2020

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

Re: K193213
Trade/Device Name: Vicks® VNT200 No Touch Forehead Thermometer, Model VNT200US
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 25, 2020
Received: March 27, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Tina Kiang, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193213

Device Name

Vicks® VNT200 No Touch Forehead Thermometer (Model Number: VNT200US)

Indications for Use *(Describe)*

The Vicks® VNT200 No Touch Forehead Thermometer is a non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a "no touch" mode, using the center of the forehead as the measurement site, on people of all ages, in a home use environment.

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

K193213

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: 10-April-2020

II. DEVICE

Name of Device: Vicks® VNT200 No Touch Forehead Thermometer
Model Number: VNT200US
Common or Usual Name: Infrared Skin Thermometer
Regulation Medical Specialty / 510k Review Panel: General Hospital
Classification Name: Thermometer, Clinical, Electronic (21 CFR 880.2910)
Regulatory Class: II
Product Code: FLL

III. PREDICATE DEVICE

Braun No Touch + Forehead NTF3000 Thermometer – 510(k) # K163516

IV. DEVICE DESCRIPTION

The Vicks® VNT200 No Touch Forehead Thermometer is a hand-held, battery-powered, infrared thermometer that converts a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead, to an oral equivalent temperature. It is calibrated for non-contact use at a distance of up to 5 centimeters (2 inches) from the center of the forehead. It uses an infrared thermopile sensor with integrated thermistor mounted in the head of the thermometer for the target reading and ambient temperature reading.

V. INDICATIONS FOR USE

The Vicks® VNT200 No Touch Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a "no touch" mode, using the center of the forehead as the measurement site, on people of all ages, in a home use environment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Element of Comparison	Subject Device: Vicks® VNT200 No Touch Forehead Thermometer	Predicate Device: Braun® No Touch + Forehead NTF3000 Thermometer	Comparison
Manufacturer (Legal)	Kaz USA, Inc., a Helen of Troy Company	Kaz USA, Inc., a Helen of Troy Company	-
Contract Manufacturer	HeTaiDa Corporation	AViTA Corporation	-
Thermometer Type	Infrared Forehead Thermometer	Infrared Forehead Thermometer	-
Models (Configuration)	Vicks® VNT200 No Touch Forehead Thermometer	The Braun® No Touch + Forehead NTF3000 Thermometer	-
510(k) Number	K193213	K163516	-
Principles of Operation	The device measures the infrared energy emitted in the area around the user's forehead	The device measures the infrared energy emitted in the area around the user's forehead	-
Intended Use	The Vicks® VNT200 No Touch Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a "no touch" mode, using the center of the forehead as the measurement site, on people of all ages, in a home use environment.	The Braun No Touch + Forehead NTF3000 Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.	Different
Labeling	Instructions for use, quick start guide, package, and rating label	Instructions for use, quick start guide, package, and rating label	Different
Features	Temperature guidance feature, and memory feature	Temperature guidance feature	Different
Components	Power / temperature measurement button, Mode button, Memory button, scanner, microcontroller, & LCD	Power button, temperature measurement button, scanner, silent mode switch, protective cap, microcontroller, & LCD	Different

Element of Comparison	Subject Device: Vicks® VNT200 No Touch Forehead Thermometer	Predicate Device: Braun® No Touch + Forehead NTF3000 Thermometer	Comparison
Sensors	The thermometer uses an infrared thermopile sensor with integrated thermistor mounted in the head of the thermometer for the target reading and ambient temperature reading.	The thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead, and an infrared proximity sensor for detection of contact or non-contact use and compensation of the temperature reading.	Different
Operating Environment (Specifications)	15°C to 40°C (59°F to 104°F); ≤ 95% Relative Humidity; 700-1060 hPA (0.7-1.06 atm)	15°C to 40°C (59°F to 104°F); ≤ 95% Relative Humidity; 700-1060 hPA (0.7-1.06 atm)	Identical
Storage Environment (Specifications)	-25°C to 55°C (-13°F to 131°F); ≤ 95% Relative Humidity; 700-1060 hPA (0.7-1.06 atm)	-25°C to 60°C (-13°F to 140°F); ≤ 95% Relative Humidity; 700-1060 hPA (0.7-1.06 atm)	Different
Measurement Range (Body Mode)	34.0°C to 43.0°C (93.2°F to 109.4°F)	34.4°C to 42.2°C (93.9°F to 108.0°F)	Different
Accuracy (Body Mode)	± 0.2°C (± 0.4°F) 35.0°C to 42.0°C (95.0°F to 107.6°F); ± 0.3°C (± 0.5°F) 34.0°C to 35.0°C (93.2°F to 95.0°F); ± 0.3°C (± 0.5°F) Above 42.0°C (Above 107.6°F);	± 0.2°C (± 0.4°F) 35.0°C to 42.0°C (95.0°F to 107.6°F); ± 0.3°C (± 0.5°F) 34.4°C to 35.0°C (93.9°F to 95.0°F); ± 0.3°C (± 0.5°F) Above 42.0°C (Above 107.6°F);	Different
Resolution of Display	0.1°C / 0.1°F	0.1°C / 0.1°F	Identical
Signal Output and Display	LCD, Buzzer	LCD, Buzzer	Identical
Measurement Distance	Up to 5 centimeters (2 inches) from the center of the forehead	Up to 5 centimeters (2 inches) from the center of the forehead	Identical

Element of Comparison	Subject Device: Vicks® VNT200 No Touch Forehead Thermometer	Predicate Device: Braun® No Touch + Forehead NTF3000 Thermometer	Comparison
MCU	Sonix SN8P1929 - a high-performance 8-bit micro-controller with 4K-word OTP ROM, 256 bytes of RAM, one 8-bit basic timer (T0) with RTC (Real Time Clock) function, two 8-bit timer counters (TC0, TC1) , a watchdog timer, five interrupt sources (T0, TC0, TC1, INT0, INT1), an in-system programming ROM (ISP ROM) register, a 16-bit ADC, a PGIA, a charge pump/regulator, an integrated LCD driver for 4-common x 24 segment LCD panel, an 8-level stack register, and a dual-clock system (high-speed clock generated from the external oscillator circuit or on-chip 16MHz high-speed RC oscillator circuit (IHRC 16MHz), low-speed clock generated from LXIN / LXOUT by 32768 crystal or RC oscillator circuit, and as a clock source for slow mode, real-time clock, & LCD function).	Weltrend WT5075F - A high-speed, high-performance and low power consumption 8-bit micro-controller, including Turbo 8052 CPU, 64K bytes embedded Flash, 256-byte direct-or-indirect-addressing SRAM, 2K-byte indirect-addressing-only SRAM, 40x4(max.) LCD driver, a Time-Base Timer, 4 multi-function timer/counters, 2-channel 12-bit PWM, 1-channel divider output, serial interface (UART and SPI), 19-channel (15 external and 4 internal) 12-bit AD converter, 4 high-performance OPs, analog switches and three clock generators (32.768kHz crystal oscillator, high-speed crystal oscillator and high-speed RC oscillator) on chip.	Different
Power Supply	Two (2), AAA batteries	Two (2), AA batteries	Different
Battery Life	At least 1000 measurements	At least 1000 measurements	Identical
Materials	User contacting materials include ABS (device housing / handle, power / temperature button, memory button, mode button), & PMMA (LCD lens).	User contacting materials include ABS (device housing / handle and power button), TPR (temperature button and forehead touch bumper), and PMMA (LCD lens and protective scanner cap).	Different
Biocompatibility	Meets ISO 10993-1:2009, 10993-5:2009, 10993-10:2010, & 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
Performance	Meets ASTM E1965:2016 and ISO 80601-2-56:2017	Meets ASTM E1965 and ISO 80601-2-56	Substantially Equivalent

Element of Comparison	Subject Device: Vicks® VNT200 No Touch Forehead Thermometer	Predicate Device: Braun® No Touch + Forehead NTF3000 Thermometer	Comparison
Electrical Safety	Meets ANSI / AAMI / IEC 60601-1:2012	Meets ANSI / AAMI / IEC 60601-1:2012	Substantially Equivalent
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2:2014	Substantially Equivalent

VII. DISCUSSION IDENTIFYING SIMILARITIES AND DIFFERENCES

Intended Use:
The subject device has been validated and is specified for non-contact ("no touch") use, up to 5 centimeters (2 inches) from the center of the forehead, which is identical to the predicate device. The predicate device has also been validated for contact use. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E1965-98. Thus, this difference does not raise any new safety or performance questions.

Labeling:

The labeling for the subject device contains additional directions describing the use of the memory feature. This does not change the safety or effectiveness of the subject device.

Features:

The memory feature of the subject device is implemented in software and hardware, whereby the most recent 10 temperature readings can be reviewed by the user by pressing the Memory button. The software was validated according to the FDA's software guidance. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E1965-98. Thus, this difference does not raise any new safety or performance questions.

Components:

Differences in components between the subject device and predicate device are limited to accessibility to different features of the devices. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E1965-98. Thus, this difference does not raise any new safety or performance questions.

Sensors:

Unlike the predicate device, the subject device does not have a separate thermistor for ambient temperature measurement, a digital, infrared proximity sensor for detection of contact or non-contact use and compensation of the temperature reading, or a parabolic mirror to help focus the infrared energy emitted from the forehead. However, both thermometers convert a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead, to an oral equivalent temperature. The same level of performance was achieved using the single sensor. This was shown with laboratory and clinical accuracy testing, validated per ASTM E1965 and ISO 80601-2-5. Therefore, the differences in internal sensors used to achieve the same effect, does not change the safety or effectiveness of the subject device.

Storage Environment:

Despite minor differences in the storage environment between the subject and predicate device, these are within the IEC 60601-1-11 and ASTM E1965 requirements, and therefore, meet these performance standards.

Measurement Range:

Despite minor differences in the measurement ranges between the subject and predicate device, these are within the ASTM E1965 requirements, and therefore, meet this performance standard.

Accuracy:

Despite minor differences in the temperature ranges over which the required accuracy is exhibited by the subject and predicate device, these are within the ASTM E1965 requirements, and therefore, meet this performance standard.

MCU:

An alternate MCU, that achieved the same functionality as the MCU used in the predicate device, was used in the subject device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E1965-98. Thus, this difference does not raise any new safety or performance questions.

Power Supply:

The subject device uses the same voltage as the predicate device, achieved with different sized batteries. This does not change the safety or effectiveness of the device.

Materials:

The subject device contains ABS and PMMA for the same components but has no TPR in its construction. The biocompatibility testing shows that the subject device complies with standards ISO 10993-1, ISO 10993-5, and ISO 10993-10. Thus, this difference does not raise any new safety or performance questions.

Other Elements of Comparison:

All other “Elements of Comparison” in the Substantial Equivalence Comparison Table are identical. The changes described above have been addressed through testing to a known performance standard or by showing equivalency in terms of function. Therefore, these differences are not significant and do not change the safety or effectiveness of the subject device.

VIII. NON-CLINICAL TESTING & PERFORMANCE DATA

The following non-clinical testing and performance data for the Vicks® VNT200 No Touch Forehead Thermometer are provided in support of the substantial equivalence determination:

Test Name	Cited Standards	Acceptance Criteria	Result
Accuracy in Test Mode	1. ASTM E1965-98:2016 2. Directive 93 / 42 EEC 3. ISO 80601-2-56:2017	In test mode the thermometer shall be within ± 0.2°C for 34-43°C or ± 0.3°C for outside of the temperature range for blackbody temperatures at 17.0, 23.0, 28.0, 29.0, 30.0, 31.0, 32.0, 33.0, 34.0, 35.0, 36.0, 37.0, 38.0, 39.0, 40.0, 41.0, & 42.0°C.	Pass
Accuracy as a Function of Supply Voltage		The thermometer shall have the same accuracy as D004327 - Accuracy in Body and Surface Modes while the thermometer is supplied 2.7V, 3.0V and 3.3V in a 37°C and 38.5°C blackbody and shall not be greater than 0.2°C change between any voltage range on a given unit	Pass
Accuracy in Range of Environments 5E	ASTM E1965-98:2016 5.6.1 / 5.6.2 ISO 80601-2-56:2017	1. In each of the five environments listed below the device shall be within 0.3°C of a blackbody at 22.5°C and within 0.2°C of a blackbody at 35, 37, 41, and 42.5°C in test mode. - Environment 1: 15-16°C with 15-25% humidity - Environment 2: 15-16°C with 85-95% humidity - Environment 3: 24-26°C with 40-60% humidity - Environment 4: 39-40°C with 15-25% humidity - Environment 5: 39-40°C with 85-95% humidity 2. In operating mode, the displayed temperature should be within permitted accuracy stated in the protocol depending on blackbody temperature and ambient temperature.	Pass
Display-Out of Range and Response Time	1. ASTM E1965-98:2016 2. Directive 93 / 42 EEC 3. ISO 80601-2-56:2017	1. In normal operating mode the thermometer shall display 'Lo' if the temperature reading is below 34°C and shall display 'Hi' if the temperature reading is above 43°C. 2. The time between the user hitting the measure button the reading being displayed on the screen is less than 2 seconds.	Pass
Current Draw in Use and Sleep Modes		The current draw shall not exceed: - 3uA in sleep mode - 15mA while the green backlight is displayed - 40mA while the yellow backlight is displayed - 30mA while the red backlight is displayed	Pass
Battery Life		The total calculated charge consumption of the thermometer in 3 years of sleep condition & 1000 readings is less than the average usable battery capacity.	Pass

Test Name	Cited Standards	Acceptance Criteria	Result
Low Battery Indication	1. ASTM E1965-98:2016 2. ISO 80601-2-56:2017	1. Above 2.5V no low battery symbol shall be displayed 2. Between 2.3V and 2.5V a low battery symbol shall be displayed on the bottom of the LCD 3. Below 2.3V the thermometer shall not turn ON 4. The thermometer shall still have the same accuracy as D004327 - Accuracy in Body and Surface Modes while the low battery indicator is present in a 37°C blackbody	Pass
Sound Level		The beeper volume shall be between 50 dB and 85 dB when measured at a distance of 2 inches from the device, measured from the front center of the LCD.	Pass
Backlight Check		1. The luminance of the backlight on the display shall be greater than: - 14cd/m^2 while the green backlight is displayed - 45cd/m^2 while the yellow backlight is displayed - 5cd/m^2 while the red backlight is displayed 2. The display shall show the corresponding backlight color during the following temperature readings: - no backlight between 34.0-35.7°C - green backlight between 35.8-37.4°C - yellow backlight between 37.5-38.5°C - red backlight between 38.6-43.0°C	Pass
LCD Display Visibility and Readability		1. The temperature display numerals shall be 7mm high and 4mm wide 2. The temperature display shall be clearly visible from a viewing angle between 5° above and 45° below the display 3. The display shall be clearly visible throughout the display angle range in low ambient temperatures (15-16°C) and high ambient temperatures (39-40°C)	Pass
Button Actuation Force & Life		1. The actuation force for the On / Off button, Mode button and Memory button shall be between 1-5N 2. The buttons shall withstand 10,000 actuations without failure	Pass
Unit Life		The thermometer shall have the same accuracy as D004327 - Accuracy in Body and Surface Modes in a 38.5°C blackbody after the unit has been through 10,000 work cycles. A work cycle is defined as turning the thermometer on, allowing the thermometer to perform a self-test, pressing the measurement button to display a temperature reading and allowing the thermometer to turn off automatically.	Pass

Test Name	Cited Standards	Acceptance Criteria	Result
Battery Door Reliability & Life		There shall be no loss of function or defects on the battery door or device after 500 cycles of removing & snapping the battery door into place.	Pass
Printing and Surface Resistance to Wiping, Cleaning and Chemicals	ASTM-E1112 5.22	The following standards shall be met after 1,000 cleaning cycles of the thermometer housing using water and 70% isopropyl alcohol: 1. Accuracy defined in D004327 2. All printing & labeling on device (including SN and LOT number) shall be clearly legible 3. All printing & labeling shall remain intact after adhesive tape is removed from the printed area at a 30° angle 4. All printing & labeling shall remain intact after being scratched with a metal tip using 3-6 N of force.	Pass
Salt Spray Storage		There shall be no rust or degradation on the battery springs, screws, PCBA or any other metal parts of the device after being in a salt spray chamber with 5% ionic concentration of salt solution for 48 hours.	Pass
Drop Test without Packaging	1. ASTM E1965-98:2016 6.3 2. ISO 80601-2-56:2017 3. IEC 60601-1:2005 + A1:2012	There shall be no evidence of damage on the visual appearance of the device or the internal components, & accuracy shall be met according to D004379 Accuracy in Range of Environments 5E Test after a 1 m free-fall drop over a hardwood board. The device will be dropped once with the IR sensor of the device parallel to the surface of the hardwood board & once through the center of the mass of the device.	Pass
Package Vibration, Drop & Compress	ISTA 2A	Compliance with ISTA 2A shall be met with the device in a master pack.	Pass
Packaging and Labelling Check	1. ASTM E1112 4.7.1 2. ASTM E1112 4.3.3.1 - 4.3.3.4 3. ASTM E1112 4.7.3 4. ASTM E1112 4.7.4 5. ASTM E1112 4.7.5 6. ASTM E1112 4.7.6.1 and 4.7.6.2 7. ASTM E1112 4.8.1	1. UDI barcode is grade C or higher 2. Labeling is completely legible 3. Artwork on the color box, Owner's Manual, & on the device shall match the approved artwork 4. The Serial No. with date of manufacture symbol present on the device	Pass
Storage	ASTM E1965-98:2016 6.1.6	The device shall be within 0.2°C on a 37°C blackbody after a 30-day storage. The devices shall be stored in low temperature storage, -25°C with <50% humidity, & will be stored in high temperature storage, 55°C with >85% humidity, for 30 days.	Pass

Test Name	Cited Standards	Acceptance Criteria	Result
Functional Software		The user interface of the device shall match the specifications outlined in D004247 User Interface Specification	Pass
Functional Software Error Handling		The error messages on the device shall match the specifications outlined in D004247 User Interface Specification for an incorrect button push, ambient temperature outside of the specified limits, & target temperature outside of the specified limits.	Pass
User Error Safety		1. There shall no permanent damage from inserting the batteries with incorrect polarization 2. There shall be no localized hot spots due to liquid buildup within the device	Pass
Electrical Safety	IEC 60601-1	Compliance with IEC 60601-1:2005 + A1:2012 from a 3rd party lab	Pass
Biocompatibility	ASTM E1112 4.6.2.2 and 5.3 ISO 10993-1:2009	Compliance with ISO 10993-1:2009 from a 3rd party lab. Compliance with ISO 10993-10:2010 for Irritation and Skin Sensitization and ISO 10993-5:2009 for In Vitro Cytotoxicity.	Pass
Electromagnetic Compatibility	IEC 60601-1-2:2015	Compliance with IEC 60601-2:2015 from a 3rd party lab	Pass
General Requirements for Basic Safety and Essential Performance	IEC 60601-1-11 2015	Compliance with IEC 60601-1-11:2015 from a 3rd party lab	Pass
Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	ASTM E1965-98:2016	Compliance with ASTM E1965-98:2016 from a third-party lab	Pass
Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56:2017	Compliance with ISO 80601-2-56:2017 from a third-party lab	Pass

BIOCOMPATIBILITY TESTING:

The biocompatibility evaluation for the Vicks® VNT200 No Touch Forehead 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 ISO 10993-1,* "*Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*," issued on June 16, 2016. The testing conducted included the following:

- Cytotoxicity
- Irritation
- Sensitization

ELECTROMAGNETIC COMPATIBILITY, BASIC SAFETY, AND ESSENTIAL PERFORMANCE:

An accredited laboratory (SGS-CSTC Standards Technical Services Co., Ltd., Guangzhou Branch) that was ISO 17025 certified, tested the Vicks® VNT200 No Touch Forehead Thermometer for electromagnetic compatibility per IEC 60601-1-2-2014, for compliance to applicable portions of ANSI / AAMI / IEC 60601-1:2012, and 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 62304:2015 – Medical device software – Software lifecycle processes*. The software for the Vicks® VNT200 No Touch Forehead 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.

IX. CLINICAL TESTING

Clinical testing of the Vicks® VNT200 No Touch Forehead Thermometer included a pivotal study of 208 subjects, 66 (32%) of which were febrile and 94 (45%) of which were male. The youngest subject enrolled was 3 days old, and the oldest subject enrolled was 69 years old.

The clinical study was conducted according to the requirements of the following standards for intermittent determination of patient temperature by electronic thermometers:

- ASTM E1965-98:2016: Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- ISO 80601-2-56:2017 – Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

X. CONCLUSION

Based on the performance testing, comparison and analysis in this submission, the subject device, the Vicks® VNT200 No Touch Forehead Thermometer, is substantially equivalent to the predicate device, the Braun® No Touch + Forehead NTF3000 Thermometer – 510(k) # K163516.