DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 21, 2017

KAZ USA, Inc., a Helen of Troy Company
Rajesh Kasbekar
Global VP of Regulatory Affairs
400 Donald Lynch Boulevard, Suite 300
Marlborough, Massachusetts 01752

Re: K163516
Trade/Device Name: Braun No Touch + Forehead NTF3000 Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 10, 2017
Received: March 22, 2017

Dear Mr. Rajesh 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,

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)*
K163516

Device Name
Braun No Touch + Forehead NTF3000 Thermometer

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K163516

I. SUBMITTER

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Phone: (508) 490-7280
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Contact Person: Rajesh S. Kasbekar, Global VP of Regulatory Affairs
Date Prepared: 1-March-2017

II. DEVICE IDENTIFICATION

Name of Device: Braun No Touch + Forehead NTF3000 Thermometer
Common or Usual Name: Infrared Forehead Thermometer
Classification Name: Thermometer, Clinical, Electronic
Regulation Number: 21CFR 880.2910
Regulatory Class: II
Product Code: FLL

III. PREDICATE DEVICE

NTF3000 No Touch + Forehead Infrared Thermometer, K134043

IV. DEVICE DESCRIPTION

The Braun No Touch + Forehead NTF3000 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 when placed in contact with the subject's forehead or within two inches of the subject's forehead.

The Braun No Touch + Forehead NTF3000 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.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Elements of Comparison	Subject Device	Predicate Device	Comparison
Device Name	Infrared Thermometer	Infrared Thermometer	Same
Models	The Braun No Touch + Forehead NTF3000 Thermometer	The NTF3000 No Touch + Forehead Infrared Thermometer	Similar

Elements of Comparison	Subject Device	Predicate Device	Comparison
510(k) Number	K163516	K134043	
Manufacturer (Legal)	Kaz USA, Inc., a Helen of Troy Company	Kaz USA, Inc., a Helen of Troy Company	Same
Contract Manufacturer	AViTA Corporation	AViTA Corporation	Same
Intended use	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.	The NTF3000 No Touch + Forehead Infrared 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.	Same
Principles of Operation	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.	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.	The fundamental operating principle of the thermometer is identical to the predicate device. There are no changes to the intended use or product specifications from the previous revision of the device. Other changes associated with software and the change in proximity sensor have been verified and validated. Therefore, it is substantially equivalent.
Measurement range	34.4°C to 42.2°C (93.9°F to 108.0°F)	34.4°C to 42.2°C (93.9°F to 108.0°F)	Same
Accuracy for body temperature measurement	± 0.2°C / 0.36°F 35.0°C to 42.0°C (95.0°F to 107.6°F); ± 0.3°C / 0.54°F 31.0°C to 35.0°C (87.8°F to 95.0°F); ± 0.3°C / 0.54°F Above 42.0°C (Above 107.6°F);	± 0.2°C / 0.36°F 35.0°C to 42.0°C (95.0°F to 107.6°F); ± 0.3°C / 0.54°F 31.0°C to 35.0°C (87.8°F to 95.0°F); ± 0.3°C / 0.54°F Above 42.0°C (Above 107.6°F);	Same
Resolution of display	0.1°C / 0.1°F	0.1°C / 0.1°F	Same
Sensor	Infrared sensor	Infrared sensor	Similar
Signal output and display	LCD, Buzzer	LCD, Buzzer	Same
Lens filter	No	No	Same
Power supply	Two (2) AA batteries	Two (2) AA batteries	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
Materials	Patient contacting materials include ABS (device housing / handle and power button) and TPR (temperature button and nose / forehead touch bumper).	Patient contacting materials include ABS (device housing / handle and power button) and TPR (temperature button and nose / forehead touch bumper).	There was no change to any material on the outside of the unit. The only material change was internal to the unit, as the analog infrared proximity sensor was changed to a digital, infrared proximity sensor.
MCU	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), an 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.	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), an 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.	Same
Performance	Meets ASTM E 1965 and ISO 80601-2-56	Meets ASTM E 1965 and ISO 80601-2-56	Same
Biocompatibility	Meets ISO 10993 and FDA Bluebook memo G95-1	Meets ISO 10993 and FDA Bluebook memo G95-1	Same
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

Based on the comparison chart above, there have been no changes to the intended use or product specifications from those of the predicate device (the NTF3000 No Touch + Forehead Thermometer), the fundamental operating principle of the thermometer is identical to that of the predicate device, and there was no change to any material on the outside of the unit from those on the predicate device. The changes associated with software and the change in proximity sensor have been verified and validated via laboratory testing and a pivotal clinical study, and through the verification and validation process, it has been shown that the differences do not raise different questions of safety and effectiveness.

VII. NON-CLINICAL PERFORMANCE DATA

The entire Hazard Analysis for the Braun No Touch + Forehead NTF3000 Thermometer was evaluated to identify all the risks / hazards that could be affected by the modifications. The following summary of non-clinical performance data are provided in support of the substantial equivalence determination:

Performance Standard	Test Performed	Acceptance Criteria	Result
IEC 60601-1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Touch current	100 µA NC; 500 µA	Pass
	Patient leakage current	10 µA NC; 50 µA SFC (d.c. current)	Pass
	Patient leakage current w/ mains on the F-type applied parts	5000 µA	Pass
	Shock / Drop test	1 meter	Pass
IEC 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Electrostatic discharge	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Pass
	Radiated RF EM fields	10 V/m; 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Pass
	Proximity fields from RF wireless communications equipment	9 – 28 V/m; 385 – 5785 MHz Multiple modulations	Pass
	Surges	± 0,5 kV, ± 1 kV	Pass
	Rated power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	Pass
IEC 60601-1-11:2015: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Ingress protection rating	IP22 per product specifications	Pass
	Operating / storage temperature range	–13 °F to 140 °F (–25 °C to 60 °C) per product specifications	Pass
	Operating / storage atmospheric pressure range	700-1060hPA (0.7-1.06 atm) per product specifications	Pass
	Operating / storage relative humidity range	15–95% non-condensing per product specifications	Pass

VIII. CLINICAL TESTING DATA

Laboratory and clinical accuracy testing was conducted on the Braun No Touch + Forehead NTF3000 Thermometer. The device complies with the following standard for intermittent determination of patient temperature by infrared thermometers:

- ASTM E1965-98:2009: Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Based on the clinical performance as documented in the pivotal clinical study, the Braun No Touch + Forehead NTF3000 Thermometer was found to be non-inferior to the predicate and reference thermometer, and therefore, substantially equivalent to the predicate thermometer.

IX. CONCLUSION

The non-clinical data support the accuracy of the device and the hardware and software verification and validation demonstrate that the Braun No Touch + Forehead NTF3000 Thermometer should perform as intended in the specified use conditions. The clinical data demonstrate that the Braun No Touch + Forehead NTF3000 Thermometer performs comparably to its predicate device, the NTF3000 No Touch + Forehead Infrared Thermometer (510(k) K134043), which was cleared for marketing in the US in May 2014 for the same intended use. Therefore, the Braun No Touch + Forehead NTF3000 Thermometer is substantially equivalent to the predicate device, the NTF3000 No Touch + Forehead Infrared Thermometer (510(k) K134043).