July 18, 2018

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: K181015
Trade/Device Name: Braun BFH175 Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 21, 2018
Received: June 22, 2018

Dear Mr. Matt J. 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. 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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181015

Device Name
Braun BFH175 Infrared Forehead Thermometer

Indications for Use *(Describe)*
The Braun BFH175 Infrared Forehead Thermometer is a non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a touch mode using 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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Section 5: 510(k) Summary K181015

I. SUBMITTER

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Contact Person: Matt J. Baun, Associate Director of Clinical & Regulatory Affairs
Date Prepared: 7-May-2018

II. DEVICE

Name of Device: Braun BFH175 Infrared Forehead Thermometer
Common or Usual Name: Infrared Skin Thermometer
Regulation Medical Specialty / 510k Review Panel: General Hospital
Classification Name: Thermometer, Clinical, Electronic (21CFR 880.2910)
Regulatory Class: II
Product Code: FLL

III. PREDICATE DEVICE

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

IV. DEVICE DESCRIPTION

The Braun BFH175 Infrared 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 when placed in contact with the subject's forehead. It uses a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings.

V. INDICATIONS FOR USE

The Braun BFH175 Infrared Forehead Thermometer is a non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a touch mode using the center of the forehead as the measurement site on people of all ages.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Element of Comparison	Subject Device: Braun BFH175 Infrared Forehead Thermometer	Predicate Device: Braun No Touch + Forehead NTF3000 Thermometer	Discussion
Manufacturer (Legal)	Kaz USA, Inc., a Helen of Troy Company	Kaz USA, Inc., a Helen of Troy Company	
Contract Manufacturer	AViTA Corporation	AViTA Corporation	
Thermometer Type	Infrared Forehead Thermometer	Infrared Forehead Thermometer	The devices have the same fundamental scientific technology and use the same physiologic temperature measurement site.
Models (Configuration)	Braun BFH175 Infrared Forehead Thermometer	The Braun No Touch + Forehead NTF3000 Thermometer	

Element of Comparison	Subject Device: Braun BFH175 Infrared Forehead Thermometer	Predicate Device: Braun No Touch + Forehead NTF3000 Thermometer	Discussion
510(k) Number	K181015	K163516	
Intended Use	The Braun BFH175 Infrared Forehead Thermometer is a non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a touch mode using the center of the forehead as the measurement site on people of all ages.	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 using the center of the forehead as the measurement site on people of all ages.	The intended use of the modified device is restricted to only the "Touch" measurement mode, which is part of the intended use of the original, predicate device.
Labeling	Instructions for use, package, and rating label	Instructions for use, package, and rating label	The change in labeling is restricted to "Touch" mode only temperature measurement and the memory feature of the modified device.
Components	Power button, temperature measurement button, scanner, silent mode switch, protective cap, microcontroller, & LCD	Power button, temperature measurement button, scanner, silent mode switch, protective cap, microcontroller, & LCD	Identical
Features	Fever Insight temperature guidance feature and memory feature	Fever Insight temperature guidance feature	The modified device has a memory feature to store the most recent temperature reading. It does not affect the safety or effectiveness of the device.
Sensor	Infrared	Infrared	Identical
Principles of Operation	The thermometer uses a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings.	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 modified device does not have a proximity sensor due to removal of "No Touch" temperature measurement mode.
Operating Environment (Specifications)	15°C to 40°C (59°F to 104°F); 15-95% Relative Humidity	15°C to 40°C (59°F to 104°F); 15-95% Relative Humidity	Identical
Storage Environment (Specifications)	-25°C to 55°C (-13°F to 131°F); 15-95% Relative Humidity 700-1060 hPA (0.7-1.06 atm)	-25°C to 60°C (-13°F to 140°F); 15-95% Relative Humidity 700-1060 hPA (0.7-1.06 atm)	The modified device has a lower storage temperature maximum limit. This does not affect the safety or effectiveness of the device.
Resolution of Display	0.1°C / 0.1°F	0.1°C / 0.1°F	Identical

Element of Comparison	Subject Device: Braun BFH175 Infrared Forehead Thermometer	Predicate Device: Braun No Touch + Forehead NTF3000 Thermometer	Discussion
Measurement Range	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)	The modified device has a slightly larger measurement range. This does not affect the safety or effectiveness of the device.
Accuracy (Specifications)	± 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) 34.0°C to 35.0°C (93.2°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) 34.4°C to 35.0°C (93.9°F to 95.0°F); ± 0.3°C (± 0.54°F) Above 42.0°C (Above 107.6°F);	Identical from 35.0°C to 42.0°C (95.0°F to 107.6°F). The modified device has a slightly larger measurement range, extending the range for which it is accurate to ± 0.3°C (±0.54°F). This does not affect the safety or effectiveness of the device.
MCU	Sonix SN8P2949 - A high-performance, 8-bit micro-controller with 8K-word OTP ROM, including 256 bytes of RAM, one 8-bit basic timer function, two 8-bit counters / timers, a watchdog timer, 6-source interrupts, in-system programming ROM function with VPP voltage generation internally for calibration data programming in ROM, a 20-bit ADC, a PGIA, three voltage regulators including AVDDR, AVE+ & VLED module for LED driving, an integrated R & C-Type LCD driver for 4-common x 32-segments LCD panel, 8-level stack register, & a dual clock system (4MHz high-speed RC oscillator, on-chip low speed RC oscillator circuit).	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.	Similar. Functionally equivalent, alternate part, which does not affect the safety or effectiveness of the device.
Power Supply	Two (2), AAA batteries	Two (2), AA batteries	Similar
Signal Output and Display	LCD, Buzzer	LCD, Buzzer	Identical
Battery Life	At least 500 readings	At least 1000 readings	Similar
Materials	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).	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).	Identical
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	No change in materials

Element of Comparison	Subject Device: Braun BFH175 Infrared Forehead Thermometer	Predicate Device: Braun No Touch + Forehead NTF3000 Thermometer	Discussion
Performance	Meets ASTM E 1965:2016 and ISO 80601-2-56:2017	Meets ASTM E 1965 and ISO 80601-2-56	Identical
Safety	Meets EN 60601-1:2014	Meets IEC 60601-1	Identical
EMC	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2	Identical

Based on the comparison chart above, there have been no changes to the intended use or product specifications of the Braun BFH175 Infrared Forehead Thermometer from those of the predicate device, the Braun No Touch + Forehead NTF3000 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 used on the Braun No Touch + Forehead NTF3000 Thermometer. The changes associated with the removal of the digital proximity sensor and updated industrial design, which include a different PCB layout, different microprocessor, and some different hardware components, have been verified and validated via laboratory testing and a pivotal clinical study. Through the verification and validation process, it has been shown that the differences do not raise new questions of safety and effectiveness.

VII. NON-CLINICAL TESTING & PERFORMANCE DATA

The entire Hazard Analysis for the Braun BFH175 Infrared Forehead Thermometer was evaluated to identify all the risks / hazards that could be affected by the modifications to the Braun No Touch + Forehead NTF3000 Thermometer.

These risks were mitigated using planned measures that included testing to recognized FDA consensus standards. Changes in software were verified and validated using the software development process. The clinical accuracy of the thermometer was validated through a multi-center, randomized clinical study. All results were within the acceptance criteria. The following table, which includes a summary of non-clinical testing data conducted according to FDA recognized consensus standards, is provided in support of the substantial equivalence determination:

Device Modification	Associated Risks	Performance Standard	Acceptance Criteria	Result
Updated industrial design with PCB layout change	Incorrect reading or minor electrical shock to user	EN 60601-1:2014:	*Touch current:* **100 µA NC; 500 µA** *Patient leakage current:* **10 µA NC; 50 µA SFC (DC current)** *Patient leakage current w/ mains on the BF-type applied parts:* **Type BF: 5000 µA**	Pass
Updated industrial design with PCB layout change	Incorrect reading	IEC 60601-1-2:2014:	*Radiated RF EM fields:* **10 V/m; 80 MHz – 2.7 GHz** *RF wireless communications equipment immunity:* **9 - 28 V/m; 385 – 5785 MHz;** **0.2 to 2.0 Watts at 1 m;** **Multiple services and modulations** *Rated power frequency magnetic fields:* **30 A/m; 50 Hz or 60 Hz**	Pass

Device Modification	Associated Risks	Performance Standard	Acceptance Criteria	Result
Updated industrial design	Incorrect reading or minor electrical shock to user	IEC 60601-1-11:2015:	*Ingress Protection:* **IP22**	Pass
Updated industrial design	Incorrect reading or minor electrical shock to user	ASTM E1965-98:2016:	*Shock / Drop:* **Absolute value of the largest error out of five (5) measurements of a blackbody at 37 ± 0.5°C, in an ambient environment of 20 - 26°C and 40 – 70% relative humidity, taken after the device is subjected to a fall from a height of 1 meter, is less than or equal to ± 0.2°C**	Pass
Removal of digital proximity sensor	Incorrect reading	ISO 80601-2-56:2017	*Bias:* **Bias for the test device should be non-inferior to the bias of the predicate device when compared to the reference, and ≤ ±0.20°C** *Standard Deviation:* **Standard Deviation for test device should be equivalent to or less than the Standard Deviation of the predicate device** *Repeatability:* **Repeatability for test device should be ≤ ±0.3°C**	Pass

VIII. CLINICAL TESTING

A controlled human clinical study was conducted using the Braun BFH175 Infrared Forehead Thermometer. The test report demonstrated that the clinical data, represented by Clinical Bias, with its Standard Deviation or Limits of Agreement, and Clinical Repeatability, met the acceptance criteria of the clinical study protocol, developed in accordance with ASTM E1965-98:2016 and ISO 80601-2-56:2017.

IX. CONCLUSION

A risk analysis was performed to identify risks associated with the device modifications. Verification and validation tests have been performed to demonstrate that the identified risks have been mitigated. The testing demonstrates that the modified Braun BFH175 Infrared Forehead Thermometer is substantially equivalent to the predicate device.