



Food and Drug Administration
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August 16, 2016

Kaz USA, Inc., A Helen of Troy Company
Ms. Amy Liu
Associate Director, Clinical and Regulatory Affairs
400 Donald Lynch Blvd., Suite 300
Marlborough, Massachusetts 01752

Re: K161933
Trade/Device Name: Braun ThermoScan[®] 3 High Speed Compact Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 11, 2016
Received: July 18, 2016

Dear Ms. Liu:

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 -S

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

Indications for Use

510(k) Number (if known)

K161933

Device Name

Braun ThermoScan® 3 High Speed Compact Ear Thermometer

Indications for Use (Describe)

The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K161933

1. Company Name and Address

Kaz USA, Inc.
A Helen of Troy Company
400 Donald Lynch Blvd., Suite 300
Marlborough, MA 01752

2. Establishment Registration Number

3006169981

3. Manufacturing Sites

Famidoc Technology Co., Ltd.

No.212 Yilong Road
Hexi Industrial Zone
Jinxia ,Changan Town
Dongguan,Guangdong Province,China.

4. Device Name

Braun ThermoScan® 3 High Speed Compact Ear Thermometer

5. Device

Classification name: Thermometer, Clinical, Electronic
Classification number – 21CFR 880.2910
Product code: FLL
Regulatory Class: II

6. Predicate Device Information

Predicate device: Famidoc FDIR-V1 - 510(k)#: K052849

7. Performance Standards

- 1) ASTM E1965-98:2003 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
- 2) IEC 60601-1 3rd edition:2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 3) BS EN ISO 15223-1: 2012: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
- 4) IEC 60601-1-2:2007: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

- 5) IEC 62366-1: 2015 Medical devices - Part 1: Application of usability engineering to medical devices.
- 6) ISO 14971:2007: Medical devices - Application of risk management to medical devices.
- 7) ISO 10993-1 / ISO 10993-5 / ISO 10993-10: Biological Evaluation of Medical Devices.

8. Indications for Use

The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.

9. Device Description and Product Change Description

The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is a hand held instrument that measures human body temperature through the opening of the auditory canal. It is a single mode ear thermometer that measures the natural thermal infrared radiation emitted from the tympanic membrane and adjacent surfaces. The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is meant for intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use environment.

10. Technological Characteristics

The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is identical to the predicated thermometer, FDIR-V1, with exception to the following changes:

- Addition of lens filter as a sanitary barrier between the infrared thermometer and the ear canal.
- Change in outer casing and associate industrial design to meet internal requirements.
- Update the brand name of the device.

11. Substantial Equivalence

Based on the comparison chart above, we believe that the Braun ThermoScan® 3 High Speed Compact Ear Thermometer is substantially equivalent to its predicate device cited above and does not raise any new safety and/or effectiveness issues.

Elements of Comparison	Subject Device	Predicate Device (Famidoc FDIR-V1)	Comparison
Device Name	Infrared Ear Thermometer	Infrared Thermometer	Similar
Models	The Braun ThermoScan® 3 High Speed Compact Ear Thermometer	FDIR-V1	Similar
510(k) Number	Pending	K052849	Similar
Manufacturer(legal)	Kaz USA, Inc., a Helen of Troy Company	Famidoc Technology Co., Ltd.	Similar
Contract Manufacturer	Famidoc Technology Co.,	Famidoc Technology	Same

	Ltd.	Co., Ltd.	
Intended for use	The Braun ThermoScan® 3 High Speed Compact Ear Thermometer is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.	The device is intended for the intermittent measurement and monitoring of human body temperature, by consumers in the home	Similar
Sensor	Infrared sensor	Infrared sensor	Similar
Microcontroller Unit	XWIC008	XWIC008	Similar
Measurement range	34.0°C~42.2°C (93.2°F~108.0°F)	32.0°C~42.9°C (89.6°F~109.2°F)	Similar (The measurement range was selected based on the range specified in ASTM E1965. This range was then included in the PRD and communicated to Famidoc (supplier) for inclusion in the engineering specification. Since this current range is a subset of the predicate device range it does not raise new questions regarding the performance and safety. All of the verification testing was completed for the selected range from ASTM E1965)
Accuracy for body temperature measurement	±0.2°C/0.4°F 35.5°C~42.0°C (95.9°F~107.6°F); ±0.3°C/0.5°F 34.0°C~35.4°C (93.2°F~95.7°F); ±0.3°C/0.5°F 42.1°C~42.2°C (107.8°F~108.0°F)	±0.2°C/0.4°F 35.5°C ~42.0°C (95.9°F~107.6°F); ±0.3°C/0.5°F 32.0°C ~35.4°C (89.6°F~95.7°F); ±0.3°C/0.5°F 42.1°C ~42.9°C (107.8°F~109.2°F)	Similar
Resolution of display	0.1°C/0.1°F	0.1°C/0.1°F	Similar
Signal output and display	LCD, Buzzer	LCD, Buzzer	Similar
Power supply	One 3V CR2032 button Li-MnO2 battery	One 3V CR2032 button Li-MnO2 battery	Similar
Fundamental Technology & Operating Principle	Uses Infrared Sensor and signal acquisition, conditioning, processing with embedded microprocessor and	Uses Infrared Sensor and signal acquisition, conditioning, processing with embedded microprocessor and	Similar

	software	software.	
Lens filter	Yes, used	No	Demonstrated to not raise questions of safety and effectiveness through requirements within standard ASTM E1965, ISO80601-2-56, ISO 10993
Performance	Meets ASTM E 1965, EN 12470-5 and ISO80601-2-56	Meets ASTM E 1965, EN 12470-5 and ISO80601-2-56	Similar
Biocompatibility	Meets ISO 10993 and FDA Bluebook memo G95-1	Meets ISO 10993 and FDA Bluebook memo G95-1	Similar
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Similar
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Similar

12. Non-clinical testing

Non-clinical performance reports were provided to document verification and validation activities which are intended to demonstrate substantial equivalence of the subject device with the noted changes, to the predicate device:

- A. Design Qualification Testing is completed to ensure that the device meets the product requirements.
 - a. Functional testing of software error handling per ASTM E1965 and ISO 80601-2-56
 - b. Functional testing of all functions after accelerated aging per ASTM F 1980-07 and ASTM D3045.
 - c. Labeling verification per requirements within ASTM E1965, ISO 80601-2-56, and IEC 60601-1
- B. Engineering testing is completed to ensure that the device meets the performance standard requirements of ASTM E1965 and ISO 80601-2-56.
 - a. Measurement accuracy after preconditioning per standard requirements:
 - Laboratory accuracy test: passed requirements per ISO 80601-2-56 Clause 201.101.2 and ASTM E1965 Clause 5.3.1
 - Clinical accuracy validation test: passed requirements per ASTM E1965 Clause 5.5
 - b. Tests for other requirements of ISO 80601-2-56 and ASTM E1965
 - Passed requirements per ISO 80601-2-56
 - Clause 201.7: ME equipment identification, marking and documents
 - Clause 201.12: Accuracy of controls and instruments and protection against hazardous outputs
 - Passed requirements per ASTM E1965
 - Clause 5.2: Displayed Temperature Range
 - Clause 5.3 Maximum Permissible Laboratory Error
 - Clause 5.5 Special Requirements

- Clause 5.6 Ambient Conditions
 - Clause 5.7 Low Power Supply Operation
 - Clause 5.8 Display and Human Interface
 - Clause 5.9 Construction
 - Clause 5.10 Labeling and Marking
 - Clause 6 Test Method
 - Clause 7 Documentation
- C. Process Validation was completed to ensure that the installation qualification, operational qualification and performance qualification were successfully completed for validating the manufacturing process.
- a. Soldering iron.
 - b. Electric screw driver.
 - c. Constant temperature water tank
 - d. Pad printing machine
 - e. Injection molding
 - f. 25C and 37C validation
- D. Biocompatibility Testing was completed in accordance with ISO-10993-1, 10993-5, 10993-10 and FDA Bluebook Memo G95-1.
- E. Usability Testing was completed in accordance with IEC 62366 and FDA Guidance Document on Human Factors titled “Applying Human Factors and Usability Engineering to Medical devices” issued on February 3, 2016.
- F. Electrical Safety, and Electromagnetic Compatibility testing was completed in accordance with IEC 60601-1:2005 and IEC 60601-1-2: 2007

13. Clinical testing

There is no change to the technological characteristics, operating principle, or intended use, of the thermometer for Braun ThermoScan® 3 High Speed Compact Ear Thermometer in comparison to the predicate device, thus clinical testing was deemed unnecessary.

14. Conclusion

Based on the performance testing and compliance with acceptable voluntary standards, we believe that the Braun ThermoScan® 3 High Speed Compact Ear Thermometer is substantially equivalent to the predicate device cited above.