DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 1, 2016

KAZ USA, Inc (a Subsidiary of Helen of Troy, Inc)
Mr. Raj Kasbekar
Vice President, Regulatory Affairs
250 Turnpike Road
Southborough, Massachusetts 01772

Re: K152748
Trade/Device Name: Braun Thermoscan® PRO 6000 Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 4, 2016
Received: December 8, 2016

Dear Mr. 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 yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

Indications for Use

510(k) Number (if known): K152748

Device Name: Braun Thermoscan® PRO 6000 Ear Thermometer

Indications for Use:

The Braun Thermoscan® PRO 6000 Ear Thermometer is indicated for the intermittent measurement and monitoring of human body temperature for patients of all ages in a professional use environment. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.

Prescription Use _____ AND/OR Over-The-Counter Use _X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kaz USA, Incorporated · 250 Turnpike Road · Southborough, MA 01772

K152748
510(k) Summary

Braun Thermoscan® PRO 6000 Ear Thermometer

1.0 Preparation Date:

February 19, 2016

2.0 Submitted By:

KAZ USA, Inc., a Helen of Troy Company
400 Donald Lynch Boulevard, Suite 300
Marlborough, MA 01752

Primary Contact Person/Prepared by:

Raj S Kasbekar, Global VP Regulatory & Clinical Affairs
KAZ USA, Inc., a Helen of Troy Company
400 Donald Lynch Boulevard, Suite 300
Marlborough, MA 01752

3.0 Device Identification:

3.1 Trade Name

Braun Thermoscan® PRO 6000 Ear Thermometer

Models:

US: PRO6000SCMN (Thermometer with Small Cradle), PRO6000LCMN (Thermometer with Large Cradle), PRO6000BSNA (Charge Dock)
[Braun Thermoscan® PRO 6000 Ear Thermometer]

3.2 Common Name

Infrared Ear Thermometer

3.3 Classification Name

Thermometer, Clinical, Electronic

(21CFR 880.2910: Product code - FLL)

4.0 Predicate Device:

Predicate	Manufacturer	Docket Number
Braun Thermoscan® PRO 4000 Ear Thermometer	Kaz USA, Inc Contract: Keytronics	K103800

5.0 Device Description:

The Braun Thermoscan® PRO 6000 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 with a built-in correction algorithm to compensate the influence of ambient temperature using a heated tip. The Braun Thermoscan® PRO 6000 Ear Thermometer also includes a technique compensation feature to detect depth of insertion to compensate for common methods of misuse, this feature uses capacitive rings mounted in the speculum of the thermometer to detect insertion and depth and measurements of the outer ear temperature during insertion to detect misuse and correct accordingly. The Braun Thermoscan® PRO 6000 Ear Thermometer is meant for professional use in hospitals and healthcare or professional office settings.

6.0 Indications for Use:

The Braun Thermoscan® PRO 6000 Ear Thermometer is indicated for the intermittent measurement and monitoring of human body temperature for patients of all ages in a professional use environment. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.

7.0 Validation Results:

Clinical Study to show substantial equivalence:

A comparison study and clinical repeatability testing was performed on the following four age groups: 0-12 months, 12 months- <5 years, 5 years- <18 years, and 18 years and older in accordance with ASTM E1965-03 to compare the Braun Thermoscan® PRO 6000 Ear Thermometer (test thermometer) with the predicate Braun Thermoscan® PRO 4000 Ear Thermometer (K103800). The reference or the gold standard used was the SureTemp Plus Oral/Rectal and Axillary Contact Thermometer in the monitoring mode (K030580). This clinical comparison study demonstrated that the Braun Thermoscan® PRO 6000 Ear Thermometer is as good as (non-inferior or substantially equivalent to) the previously approved Braun Thermoscan® PRO 4000 Ear Thermometer in all age groups with respect to the bias and standard deviation in comparison to the Reference SureTemp Plus Oral/Rectal and Axillary Contact Thermometer in the monitoring mode (K030580). The temperatures obtained with the test Infrared Ear Thermometer were highly related when compared to the predicate device, where temperatures were

measured in the oral mode for children above 5 years) and axillary mode (for children under 5 years) . The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM E1965-03 standard were within clinical acceptability (bias less than predicate device when compared to reference). The clinical repeatability of the Infrared Ear Thermometer was statistically and clinically acceptable (less than 0.3 deg C or 0.58 deg F).

8.0 Device Comparison with Predicate

8.1 Intended Use

The predicate device, the Braun Thermoscan® PRO 4000 Ear Thermometer is intended for the intermittent determination of the human's body temperature for people of all ages. The intended use and indications for use of the predicate and the Braun Thermoscan® PRO 6000 Ear Thermometer are similar. The predicate device as well as the KAZ Braun Thermoscan® PRO 6000 Ear Thermometer use the ear as the measurement site.

8.2 Materials

Materials used in the manufacture of the Braun Thermoscan® PRO 6000 Ear Thermometer are similar (derived from similar resins) to the predicate device. All skin contacting materials used in the new thermometer have been tested for biocompatibility (cyto-toxicity in accordance with ISO 10993-5 as well as irritation and sensitization in accordance with ISO 10993-10) and FDA Blue book memo G 95-1 for both thermometers and the corresponding test reports are included in this submission.

8.3 Design

The industrial design of the KAZ Braun Thermoscan® PRO 6000 Ear Thermometer is identical to the predicate device except for a new outer shell.

8.4 Operational Principles

The Braun Thermoscan® PRO 6000 Ear Thermometer is a handheld device, containing an On/Off switch, sensor area, microcontroller and LCD screen to control the device and take measurements. The operating principle is based on detection of infrared energy and use of predictive algorithms to estimate the body temperature.

8.5 Technology

The technology of the Braun Thermoscan® PRO 6000 Ear Thermometer is identical to the predicate device. The technique compensation feature is additional technology that is integrated into the Braun Thermoscan® PRO 6000 Ear Thermometer using additional hardware (three capacitive rings) and software.

8.6	**Comparison table between test**	**and Predicate Devices**	
SE Comparisons	**Subject (Braun Thermoscan® PRO 6000 Ear Thermometer)**	**Predicate (Braun Thermoscan® PRO 4000) K103800**	**Comment**
Classification	21CFR 880.2910	21CFR 880.2910	Same
Product Code	FLL	FLL	Same
FDA Class	II	II	Same
Intended Use	A non-sterile, re-useable clinical thermometer intended for the intermittent determination of the human's body temperature for people of all ages	A non-sterile, re-useable clinical thermometer intended for the determination of the human's body temperature for people of all ages.	Same
Operation	Hand held-Manually operated	Hand held-Manually operated	Same
Sensor	Infrared	Infrared	Same
Materials	Common Materials- including an impact resistant casing. Biocompatible metals and resins.	Common Materials- including an impact resistant casing. Biocompatible metals and resins.	Similar – validated for cytotoxicity per ISO10993-5 and irritation as well as sensitization per ISO 10993-10
Dimensions	150mm x 60 mm x 35mm	150mm x 45 mm x 30 mm	Similar
Accuracy	0.3 deg C for <35 deg C 0.2 deg C for 35 deg C to 42 deg C 0.3 deg C for >42deg C	0.3 deg C for <35.5 deg C 0.2 deg C for 35.5 deg C to 42 deg C 0.3 deg C for >42 deg C	Meets ASTM E1965, EN12470-5 and ISO 80601-2-56
Precision (SD)	<0.6 deg C	<0.6 deg C	Same
Repeatability	<0.3 deg C	< 0.3 deg C	Meets EN 12470-5
Operating temperature	10 to 40 deg C ambient temperature (amb) and up to 95% RH	10 to 40 deg C ambient and up to 95% RH	Same
Measurement Range	20 deg C to 42.2 deg C	20 deg C to 42.2 deg C	Same
Display	LCD	LCD	Same
Response Time	2-3 sec	2-3 sec	Same
Measurement Site	Ear	Ear	Same
Scale	Deg F/Deg C	Deg F/Deg C	Same
Power Supply	Two AA Alkaline Batteries or Custom Nickel Metal Hydride Battery Pack	Two AA Alkaline Batteries or custom rechargeable Nickel Metal Hydride Battery Pack	Same
Standards Met for Bench and Clinical Performance	1) ASTM E1965-1998: 2009 Infrared Thermometers for Intermittent Determination of Patient temperature 2) Clinical accuracy test requirements established in the standard ASTM E1965-09 (Clinical part only)- Standard Specification for Infrared Thermometer	Same	All standards verified and validated for test device and met acceptance criteria.

	For Intermittent Determination of Patient Temperature; 3) IEC 60601-1 3rd edition:2005 Medical Electrical Equipment: General requirements for Safety, Requirements and Tests. 4) IEC 60601-1-2: 2007 Medical Electrical Equipment- Part 1: General Requirements for Safety, Electromagnetic Compatibility- Requirements and Tests. 5) AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing- and appropriate Parts 6) ISO 10993-5: Biological Evaluation of Medical Devices: Part 5: Tests for In-vitro cytotoxicity. 7) ISO 10993-10: Biological Evaluation of Medical Devices: Part 10: Tests for Irritation and Sensitization. 8) ISO 14971:2012: Application of Risk Management to Medical Devices 9) EN IEC 62304:2006 Medical Device Software – Software life-cycle processes 10) IEC EN62366:2007 Applicability of Usability Engineering to Medical Devices – Collateral Standard: Usability 11) ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good Clinical Practice (also includes 21CFR812, parts 50 and 56)		

9. Conclusion:

Based on the performance testing and compliance with acceptable voluntary standards, we believe that the Braun Thermoscan® PRO 6000 Ear Thermometer is substantially equivalent to its predicate device cited above.