July 28, 2021

Huaian Zhongxin Packing Material Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K203431
Trade/Device Name: Disposable Ear Thermometer Probe Cover
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 1, 2021
Received: July 9, 2021

Dear Boyle Wang:

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,

CAPT Alan M. Stevens
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203431

Device Name
Disposable Ear Thermometer Probe Cover

Indications for Use *(Describe)*
The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.
The probe cover is provided non-sterile and for single use only.

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

(K203431)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Contact: Feng Zuo
Date of Preparation: July.24,2021

Designated Submission Correspondent

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Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Disposable Ear Thermometer Probe Cover
Common name: Thermometer Probe Covers and Sheaths
Classification name: Clinical electronic thermometer
Model(s): 4#,6#

3.0 Classification

Production code: FLL
Regulation number: 21CFR 880.2910
Classification: Class II
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Kaz, USA Inc.
Device: Braun Thermoscan® Pro 4000 Series/IRT 4000 Series

Thermometers
510(k) number: K101747

5.0 Device Description

The Disposable Ear Thermometer Probe Cover is a disposable plastic cover made of a biocompatible polypropylene material that is dimensionally manufactured to set tolerances so that it can be fitted on the probe tip of the thermometer. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal to prevent any ear secretions or particulates from being transferred between different people.

The subject device is used as barriers between Braun Thermoscan® PRO3000 series/PRO4000 series/PRO6000 series ear thermometer, and also compatible with Braun Thermoscan® IRT1020/IRT2020/IRT2520/IRT3020/ IRT3520/IRT4020/IRT4520/IRT6020/IRT6520 ear thermometer and users' auditory canal measuring sites to avoid possible contamination and infection during temperature measuring.

The probe covers are transparent, colorless and odorless, non-sterile and intended for single use only.

6.0 Indication for Use Statement

The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal. The probe cover is provided non-sterile and for single use only.

7.0 Comparison to the Predicate Device

Item	Subject Device K203431	Predicate Device K101747	Remark
Type of Thermometer	Disposable Ear Thermometer Probe Cover	Probe Cover	--
Product Code	FLL	FLL	Same
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	Same
Class	II	II	Same
Indications for use	The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal. The probe cover is provided non-sterile and for single use only.	The Braun Thermoscan®IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometers is indicated	Same*

		for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.	
Prescription/over-the-counter use	Over-the-counter use	Over-the-counter use	Same
Design Features	Conforms to ASTM Standard E1104	Conforms to ASTM Standard E1104	Same
Design Configurations	One size	One size	Same
Performance Specifications	Conforms to ASTM Standard E1104	Conforms to ASTM Standard E1104	Same
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Same
Patient contact materials	Polypropylene	Polypropylene	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

*The predicate's thermometer probe covers are accessories to the thermometer itself, and were included in its 510(k) clearance under K101747.Only the probe covers are included in this current 510(k),as there is no thermometer or any accessory marked with the current subject device. The subject device's indications are only applicable to the probe covers. The proposed device's Indications for Use are, therefore, more narrow than the Indications for Use stated in K101747, which applied to both the thermometer and the probe covers, as the subject device's indications are only applicable to the probe covers.

8.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the subject devices met all design specifications as were Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM E1104-98 (Reapproved 2016) Standard Specification for Clinical Thermometer Probe Covers and Sheaths.
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

9.0 Summary of Clinical Testing

Clinical testing was not required for this submission.

10.0 Conclusion

Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. Based on the performance testing and compliance with acceptable voluntary standards, the subject device is substantially equivalent to its predicate device in K101747.