May 20, 2021

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd
Yuzhuo Wang
Medical Device Registered Engineer
Yunyang Industrial Park, Danyang, Jiangsu, China
Jiangsu, Jiangsu 212300
China

Re: K203583
Trade/Device Name: YUWELL Infrared Ear Thermometer: YHT101, YHT200
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 13, 2021
Received: April 20, 2021

Dear Yuzhuo 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,

Payal Patel
Acting 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)*
K203583

Device Name
YUWELL® Infrared ear thermometer：YHT101,YHT200

Indications for Use *(Describe)*
The YUWELL® Infrared ear thermometer is a non-sterile, reusable clinical thermometer. The device is to display the body temperature in the ear cavity by thermal radiation for people of all ages except preterm babies and newborns (1-29 days old).

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

OWNER/SUBMITTER'S INFORMATION

Company Name: Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.

Company Address: Yunyang Industrial Park, Danyang, Jiangsu Province,P.R. China, 212300

Contact: Wang, Yuzhuo

Phone: 0511-86900827

Fax: 0511-86900991

Email: wang.yz@yuyue.com.cn

Date prepared: November 20, 2020

TRADE NAME, COMMON NAME, CLASSIFICATION

Trade Name: YUWELL® Infrared ear thermometer

Common Name: Infrared ear thermometer

Model: YHT101, YHT200

Classification Name: Thermometer, Clinical, Electronic

Product Code: FLL

Regulation Number: 880.2910

Device Class: Class Ⅱ

IDENTIFICATION OF PREDICATE DEVICE(S)

The identification of predicates within this submission is as follow:

Manufacturer: KAZ USA, Inc (a Subsidiary of Helen of Troy, Inc)

Trade Name: Braun Thermoscan® PRO 6000 Ear Thermometer

Common Name: Infrared Ear Thermometer

Product Code: FLL

Classification Name: Thermometer, Clinical, Electronic

Regulation Number: 21 CFR 880.2910

Classification: Class Ⅱ

FDA 510 (k) #: K152748

DESCRIPTION OF THE DEVICE

The YUWELL® Infrared ear thermometer is designed for measuring the body's temperature, is a hand-held non-contact infrared thermometer, battery powered, using the infrared energy emitted in the subject's tympanic membrane that converts a user's body temperature.

The subject device is simple and convenient to use. The temperature measurement takes only 2 second. The YUWELL® Infrared ear thermometer is intended for use on people of all ages except preterm babies and newborns (1-29 days old).

INTENDED USE

The YUWELL® Infrared ear thermometer is a non-sterile, reusable clinical thermometer. The device is to display the body temperature in the ear cavity by thermal radiation for people of all ages except preterm babies and newborns (1-29 days old).

TECHNOLOGICAL CHARACTERISTIC

The ear thermometer is equipped with an infrared sensor, which can transform the infrared light released by human ear membrane into corresponding electrical signal. The signal is corrected by the amplifier and signal processing circuit according to the internal algorithm of the instrument and the targeted emissivity, and then transformed into the temperature value of the measured human body.

SUBSTANTIAL EQUIVALENCE

Comparison of technological characteristics

Description	**Subject Device（K203583）**	**Predicate Device (K152748)**	**SE Discussion**
Manufacturer	JiangSu YuYue	BRAUN (Germany)	-
Product name	Infrared ear thermometer	ThermoScan® Ear Thermometer	-
Model	YHT101, YHT200	PRO 6000	-
Patients population	People of all ages except preterm babies and newborns (1-29 days old).	People of all ages	Note No. 1
Product Code	FLL	FLL	Same
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	Same
Classification	II	II	Same
Intended Use	The YUWELL® Infrared ear thermometer is a non-sterile, reusable clinical thermometer. The device is to display the	A non-sterile, re-useable clinical thermometer intended for the intermittent determination of the human's body	Note No. 2

	body temperature in the ear cavity by thermal radiation for people of all ages except preterm babies and newborns (1-29 days old).	temperature for people of all ages	
Product principle	The ear thermometer is equipped with an infrared sensor, which can transform the infrared light released by human ear membrane into corresponding electrical signal. The signal is corrected by the amplifier and signal processing circuit according to the internal algorithm of the instrument and the targeted emissivity, and then transformed into the temperature value of the measured human body.	The ear thermometer is equipped with an infrared sensor, which can transform the infrared light released by human ear membrane into corresponding electrical signal. The signal is corrected by the amplifier and signal processing circuit according to the internal algorithm of the instrument and the targeted emissivity, and then transformed into the temperature value of the measured human body.	Same
Product structure	Consists of shell, buttons, circuit board, and batteries	Consists of shell, buttons, circuit board, and batteries	Same
Operation	Hand held-Manually operated	Hand held-Manually operated	Same
Sensor	Infrared	Infrared	Same
Measurement Range	34.0°C to 42.2°C (93.2℉ ~108.0℉)	20°C to 42.2°C (68°F to 108.0°F)	Note No. 3
Accuracy	34.0℃~34.9℃(93.2℉ ~94.8℉),±0.3℃(±0.5℉) 35.0℃~42.0℃(95.0℉ ~107.6℉),±0.2℃(±0.4℉) 42.1℃~42.2℃(107.7℉ ~108.0℉),±0.3℃(±0.5℉)	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	Note No. 4
Display	LCD	LCD	Same
Measurement Site	Ear	Ear	Same
Dimensions	YHT101: 145mm x 37 mm x 57mm YHT200: 143mm x 39 mm x 57mm	150mm x 60 mm x 35mm	Similar
Materials	YHT101: Shell: ABS material Button: PC material	Common Materials-including an impact resistant casing. Biocompatible metals and	Similar – validated for cytotoxicity per

	YHT200: Shell: ABS material Button: ABS material	resins.	ISO10993-5 and irritation as well as sensitization per ISO 10993-10
Scale	°C/°F	°C/°F	Same
Resolution of display	0.1ºC/0.1ºF	0.1ºC/0.1ºF	Same
Operating Mode	Adjusted mode	Adjusted mode	Same
Energy Source	Two (2) AAA alkaline batteries	Two (2) AA batteries or Custom Nickel Metal Hydride Battery Pack	Note No. 5
Automatic power off time	60s±10s	10s	Note No. 6
Operating Environment	Temperature: 10℃-40℃(50 ºF-104 ºF); Humidity: 15% RH ~ 90% RH (non-condensing); Atmospheric pressure: 70kPa-106kPa;	Temperature: 10℃-40℃ (50 ºF-104 ºF) and up to 95% RH ;	Note No.7
Storage Environment	Temperature: -20 ºC ~ +55 ºC (-4 ºF-131 ºF) Humidity: 15% RH ~ 90% RH (non-condensing) Atmospheric pressure: 70kPa-106kPa	Temperature: -25 ºC ~ +55 ºC (-13 ºF-131 ºF) Humidity: 15% RH ~ 95% RH (non-condensing)	Note No.8
Control button	Measure button Memory button	Measure button C/F button Memory button Timer button	Note No.9
Memory function	YHT101: 7 groups of measured values can be memorized YHT200: 10 groups of measured values can be memorized	Memorize the last temperature measured.	Note No.10
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same
Performance	Meets ASTM E 1965 and ISO 80601-2-56	Meets ASTM E 1965 and ISO 80601-2-56	Same

Biocompatibility	Meets ISO 10993-1 (includes US FDA Blue book memo G95-1-100 Title) ISO 10993-5 ISO 10993-10	Meets ISO 10993-1 (includes US FDA Blue book memo G95-1-100 Title) ISO 10993-5 ISO 10993-10	Same

DISCUSSION OF DIFFERENCES

Note ID	Justification
Note No.1 and Note No.2	According to the literature 'Temperature Control in Preterm Infants-Effect of Birthweight and Gestational Agenei, preterm babies has a lower body temperature than a normal fetus just after birth. Therefore, in order to reduce the risk of the product, the scope of the applicable group of people has been narrowed down to exclude: preterm babies and newborns (1-29 days old).The subject device has a narrow applicable population and it will not raise any new or different safety or effectiveness risks.
Note No.3 and Note No.4	The measurement range of the predicate device is larger than that of the subject device. The scale of clinical thermometer like Mercury thermometer reads temperature from 35°C to 42°C. The subject device measurement range is 34.0°C to 42.2°C meet the normal clinical use. For the normal clinical measurement range of 34.0°C to 42.2°C, the accuracy of the subject device and the predicate device are the same. So the measurement range and accuracy difference does not bring additional clinical risks.
Note No. 5	The subject device and the predicate device use different batteries. The subject battery-related performance has been tested through the applicable IEC standards, and the report proves that the subject equipment powered by two AAA alkaline batteries is qualified.
Note No. 6	The subject device has about 60 seconds automatic power off time and it's longer than the 10 seconds of the predicate device. The design purpose is to give the user more time to review or record the data if needed. The difference will not raise any new safety or effectiveness risk.
Note No.7 and Note No.8	Although the operation and storage conditions of the subject device are slightly different from the predicate device, they meet the same standard requirements of ISO 80601-2-56 and IEC 60601-1-11. Therefore, the operating and storage conditions will not influence the safety and effectiveness of the product.

Note No.9	The difference of button doesn't influence function of the device according to the performance test, which will not raise issues in safety and effectiveness.
Note No.10	In terms of the memory function, it is to help patients remember and check the previous results, so this would not raise any safety and efficacy problems.

SUMMARY OF TESTING (BENCH AND CLINICAL PERFORMANCE):

The design and manufacturing of YUWELL® Infrared ear thermometer are subject to verification and validation testing in conformance with regulatory guidance and recognized consensus standards.

- Performance test according to ASTM E 1965 and ISO80601-2-56
- Clinical accuracy test requirements established in the standard ASTM E1965 (Clinical part only) and ISO 80601-2-56（Clinical accuracy validation only)
- Software verification and validation according to the requirements of FDA "Guidance for the content of premarket submissions for software contained in Medical Devices"
- Biocompatibility test according to ISO10993 and FDA Bluebook memo G95-1
- Electrical safety test according to IEC60601-1
- Electromagnetic compatibility test according to IEC60601-1-2
- Home use test according to IEC60601-1-11

CONCLUSION :

The subject device has similar intended use, performance, equivalence testing standards, and all testing results have come back as positive results or pass for the subject device, which the subject device is as safety and effectiveness as the predicate device.

The differences above between the subject device and predicate device do not affect the intended use, technology characteristics, safety and effectiveness. And no issues are raised regarding to safety and effectiveness.