December 6, 2020

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Caixia Yang
Quality Assurance
Yunyang Industrial Park, Danyang, Jiangsu
Danyang, 212300
China

Re: K201864
Trade/Device Name: YUWELL Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 26, 2020
Received: July 6, 2020

Dear Caixia Yang:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*
K201864

Device Name

YUWELL Infrared Thermometer : YT-1,YT-l A,YT- lB,YT-l C,YT-2,YT-2A,YT-2B,YT-2C

Indications for Use *(Describe)*
The YUWELL® Infrared thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except preterm babies.

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

D 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: K201864

This 510(k) Summary is in conformance with 21CFR 807.92

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: Yuzhuo Wang

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TRADE NAME, COMMON NAME, CLASSIFICATION

Trade Name: YUWELL® Infrared Thermometer, YT-1,YT-l A,YT- lB,YT-l C,YT-2,YT-2A,YT-2B,YT-2C

Common Name: Infrared Thermometer

Classification Name: Thermometer, Clinical, Electronic

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Device Class: Class Ⅱ

IDENTIFICATION OF PREDICATE DEVICES(S)

The identification of predicates within this submission is as follow:

Manufacturer: Kaz USA,Inc.,a Helen of Troy Company

Trade Name: Braun No touch + Forehead NTF3000 Thermometer

Common Name: Infrared Forehead Thermometer

Product Code: FLL

Classification Name: Thermometer, Clinical, Electronic

Regulation Number: 21 CFR 880.2910

Classification: Class Ⅱ

FDA 510 (k) #: K163516

5.4 DESCRIPTION OF THE DEVICE

The YUWELL® infrared thermometer is designed for measuring the body's frontal temperature, is a handheld non-contact infrared thermometer, battery powered, using the infrared energy emitted in the subject's forehead area within 0-5cm that converts a user's forehead temperature. The measurement reference sites is the center of the brow.

The temperature measurement takes only 1 second, does not contact human skin. The infrared thermometer is intended for use on people of all ages except pre-term babies.

5.5 INTENDED USE

The YUWELL® Infrared thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non- contact mode on the center of the forehead as the measurement site on people of all ages except preterm babies.

5.6 TECHNOLOGICAL CHARACTERISTIC

Measure human body temperature.Therefore, once the operator approaches the specific part of the human body (forehead) according to the use method, and presses the measurement key, the infrared radiation receiving sensor can be activated immediately, and the thermal energy generated by the arterial blood flow can be detected quickly through the infrared sensor, so as to accurately measure the human body temperature.

5.7 SUBSTANTIAL EQUIVALENCE

Comparison of technological characteristics

Description	Subject Device （K201864）	Predicate Device (K163516)	SE Discussion
Device Name	Infrared Thermometer	Infrared Thermometer	Same
Product Code	FLL	FLL	Same
Regulation No.	880.2910	880.2910	Same
Classification	II	II	Same
Intended Use	The YUWELL® Infrared thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except preterm babies.	The Braun No Touch + Forehead NTF3000 Thermometer is a nonsterile, reusable clinical thermometer intended for the intermittent determinati on of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.	Note No.1
Patient Population	People of all ages except preterm babies.	People of all ages	Note No.2
Technological Characteristics	The thermometer uses a thermopile sensor and thermistor for the target reading. A thermistor mounted	The thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor	Same

	in the head of the thermometer for ambient temperature readings and compensation of the temperature reading. A parabolic mirror to help focus the infrared energy emitted from the forehead. An infrared proximity sensor for detection of non-contact use.	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.	
510 (k) Number	K201864	K163516	N/A
Design Method	Using infrared energy conversion	Using infrared energy conversion	Same
Display	Backlight LCD Digital Display	Backlight LCD Digital Display	Same
Sensor	Infrared sensor、Digital Proximity Sensor	Infrared sensor、Digital Proximity Sensor	Same
Operation	Hand held-Manually operated	Hand held-Manually operated	Same
Measurement Site	Forehead	Forehead	Same
Operating Mode	Adjusted Mode	Adjusted Mode	Same
Ranging Function	YT-1, YT-1A, YT-2, YT-2A have ranging function, YT-1B, YT-1C, YT-2B, YT-2C have no ranging function.	Have ranging Function	Note No.3
Vibration Function	YT-1, YT-1B, YT-2, YT-2B have vibration function, YT-1A, YT-1C, YT-2A, YT-2C have no vibration function.	No vibration Function	Note No.4
Scale	°C/°F	°C/°F	Same
Signal Output and Display	LCD, Buzzer	LCD, Buzzer	Same
Measurement Range	32.5°C to 43.0°C (90.5°F to 109.4°F)	34.4°C to 42.2°C (93.9°F to 108.0°F)	Note No.5

Accuracy	±0.2℃(±0.4℉) in the range of 35.0℃～42.0℃(95.0℉～107.6℉) ± 0.3 ℃ (± 0.5 ℉)in the range of 32.5℃～34.9℃ (90.5 ℉ ～ 94.8 ℉) and 42.1℃～43.0℃(107.8 ℉～109.4℉)	± 0.2°C/0.4°F for the range 35.0°C to 42.0°C (95.0°F to 107.6°F); ± 0.3°C /0.5°F(outside this temperature range)	Note No.6
Resolution of display	0.1ºC/0.1ºF	0.1ºC/0.1ºF	Same
Operating Environment	Temperature: +10 ºC ~ +40 ºC (50 ºF-104 ºF) Humidity: 15% RH ~ 90% RH (no condensation)	Temperature: +15ºC ~ +40 ºC (59 ºF-104 ºF) Humidity: 15% RH ~ 95% RH (no condensation)	Note No.7
Storage Environment	Temperature: -20 ºC ~ +55 ºC (-4 ºF-131 ºF) Humidity: 15% RH ~ 90% RH (no condensation)	Temperature: -25 ºC ~ +60 ºC (-13 ºF-140 ºF) Humidity: 15% RH ~ 95% RH (no condensation)	Note No.8
Memory Size	No data stored for YT-1, YT-1A, YT-1B, YT-1C Up to 10 sets of data for YT-2, YT-2A, YT-2B, YT-2C	No data stored	Note No.9
Energy Source	Two (2) AAA batteries	Two (2) AA batteries	Note No.10
Display Content	YT-1 Series:Distance prompt/Voice prompt/battery reminder/result display/temperature unit/distance unit YT- 2 Series:Distance prompt/Voice prompt/battery reminder/result display/temperature unit/distance unit/Memory symbol	Distance prompt/Voice prompt/battery reminder/result display/temperature unit/distance unit	Note No.11

Controls	YT-1 Series:Power ON Measurement button/Prompt tone key YT-2 Series:Power ON Measurement button/Memory button	Power button/Temperature button/Silent mode switch	Note No.12
Measurement distance	Within 0-5cm	Within 0-5cm	Same
Touch aspect	Non contact	Non contact	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 and FDA Bluebook memo G95-1	Meets ISO 10993 and FDA Bluebook memo G95-1	Same
Electrical Safety	Meets IEC 60601-1	Meets IEC 60601-1	Same
EMC	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Same

5.8 DISCUSSION OF DIFFERENCES

Note ID	Justification
Note No.1 and Note No.2	The infrared thermometer produced by our company can meet the requirements of measuring all groups of people, but 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.The products are safe and effective and not affected within the applicable scope.
Note No.3 and Note No.4	Vibration function: After the body temperature is measured, the product body will vibrate to remind the user that the test has been completed. Ranging function: When the measurement distance is more than about 5 cm, the word "0- 5"will be displayed on the screen. When the measurement distance is less than about 5 cm, the device will automatically measure. The ranging and vibration assist function of the device is only used as a reminder for measuring distance requirements and after measurement. This does not affect the safety or effectiveness of the device.
Note No.5 and Note No.6	The measurement range of the subject device is slightly larger than that of the predicate device. At 34.4℃-42.2℃, the accuracy is the same.Due to the difference in the measurement range, the accuracy is different: the subject device has a larger measurement range than the predicate device, so the subject device has increased the accuracy requirements in the range of 32.5℃-34.3℃ and 42.3℃-43.0℃. The measurement range and accuracy have been verified, so the efficacy and safety of the device will not be affected.

Note No.7 and Note No.8	The gaps of operating temperature and humidity are verified with aging testing and transportation simulation testing, the results demonstrated that the temperature and humidity are met the product requirements, which will not influence the safety and effectiveness of the devices.
Note No.9	The subject devices have 8 models. The functions of these models are a little different. But all of the differences would not influence the safety of the device. 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.
Note No.10	Passing the aging test, use the new battery for no less than 3000 measurements, which will be enough for the patients.
Note No.11	The main functions of the subject device and predicates are really similar, so display of contents of the device depends on the functions of the devices, In terms of the memory display, it is to help patients remember and check the previous results, given the freedom of choice to patients does not affect the safety and effectiveness of the devices.
Note No.12	The difference of button doesn't influence function of the device, which will not raise issues in safety and effectiveness.

5.9 SUMMARY OF NON-CLINICAL TESTING (BENCH):

The design and manufacturing of YUWELL® Infrared 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
- 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

5.10 CONCLUSION:

The subject device has same intended use, similar 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.