December 10, 2021

Kangfu Medical Equipment Factory
Jixiang Zhang
Quality Manager
No.380 Ningkang East Road,
Lecheng Town, Yueqing
Wenzhou, ZheJiang 325699
China

Re: K201600
Trade/Device Name: Infrared thermometer, models KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 7, 2021
Received: November 10, 2021

Dear Jixiang Zhang:

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,

Gang Peng For
Payal Patel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201600

Device Name
Infrared thermometer, models KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28

Indications for Use *(Describe)*
The infrared thermometer, models KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28 is designed to measuring human body temperature through ear or forehead in the healthcare environments or home use and is non-sterile. The thermometer is a reusable device intended for people of all ages except neonates/newborns.

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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51O(k) Summary

1. Submitter:

Table 1 Submitter {Owner) and Contact Information

Company / Institution Name			
Kangfu Medical Equipment Factory			
Phone Number {including area code)	**FAX Number {including area code)**		
+86 0577-62579618	N.A.		
Street Address			
No.380 Ningkang East Road, Lecheng Town, Yueqing			
City	**State/Province**	**ZIP/Postal Code**	**Country**
Wenzhou	Zhejiang	325699	China
Contact Name			
Jixiang Zhang			
Contact Title	**Contact E-mail Address**		
Quality Manager	416548914@qq.com		

Date Prepared: 2021-12-07

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

2. Device Information:

Type of 510(k) submission: Traditional

Device Name: Infrared Thermometer

Models: KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28.

Classification name: thermometer, electronic, clinical

Review Panel: General Hospital

Product Code: FLL

Device Class: II

Regulation Number: 880.2910

In Vitro Diagnostic Device: Not applicable, the subject device is not an In Vitro Diagnostic Device per the classification defined above.

Class Ill Device Statement: Not applicable, the subject device is Class II per the classification defined above.

3. Predicate device:

Sponsor: Shenzhen Brav Electronic Technologies Co., Ltd

Product Name/ Model: Infrared Thermometer, Model EFT-165

Classification name: thermometer, electronic, clinical

Device Class: II

Regulation Number: 880.2910

510(K) Number: K171214

4. Indications for Use

The infrared thermometer, models KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28 is designed to measure human body temperature through ear or forehead in healthcare environments or home use and is non-sterile. The thermometer is a reusable device intended for people of all ages except neonates/newborns.

5. Basic principle

Any object in which temperature is higher than absolute zero degree will transmit some infrared radiation energy according to its own temperature. The radiation energy and its distribution per wavelength are closely associated with its surface temperature. Based on this principle, it is possible to measure the forehead or ear temperature and then adjust the offset between forehead or ear temperature and actual body temperature, which will result in the correct display of body temperature.

6. Device Description

The KFT series infrared thermometer measures the body temperature through receiving the infrared energy radiation from the surface of human body. It is capacified with forehead mode and ear temperature mode, directly shown on the LCD screen.

- The device is widely used for home healthcare and medical environment.
- The product is mainly comprised of infrared temperature sensors, signal receiving processor, buttons, buzzer, LCD display, battery, etc.
- It focuses the infrared from the human's forehead or ear by the Fresnel lens.

7. Comparison to predicate device

Table 2 Similarity and difference analysis between Subject Device and Predicate Device

ITEM	**Subject Device**	**Predicate Device K171214**	**Comparison Result**
Manufacture	Kangfu Medical Equipment Factory	Shenzhen Brav Electronic Technologies Co., Ltd.	
Model	KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28	EFT-165	
Regulation information	Product Code: FLL Device Class: II Regulation Number: 880.2910 Classification name: thermometer, electronic, clinical	Product Code: FLL Device Class: II Regulation Number: 880.2910 Classification name: thermometer, electronic, clinical	Same
Type of use	Over-the-counter Use	Over-the-counter Use	Same
Indications for Use	The infrared thermometer, models KFT-22M, KFT-22, KFT-23, KFT-24, KFT-25, KFT-26, KFT-27, KFT-28 is designed to measuring human body temperature through ear or forehead in the healthcare	The infrared thermometer is intended for the measurement and monitoring of human body temperature by doctors or customers in the hospital or at home.	Different [1]

	environments or home use and is non-sterile. The thermometer is a reusable device intended for people of all ages except neonates/newborns.		
Intended patient population	People of all ages except neonates/newborns	People of all ages more than three months	
Measuring position	Forehead and ear	Forehead and ear	Same
Measuring mode	Forehead temperature mode and ear temperature mode	Forehead temperature mode, and ear temperature mode	Same
Measuring Distance for forehead mode	3 cm, Non - Contact	0cm, Contact	Different [2]
Measuring Distance for ear mode	0cm, Contact	0cm, Contact	Same
Measurement time	10 s	10 s	Same
Measurement time between measurements	5s	5s	Same
Use of forehead probe cover	YES, switch to the forehead mode when attach the probe cover	YES, switch to the forehead mode when attach the probe cover	Same
Detection method	Temperature is detected by The sensor and calculated.	Temperature is detected by The sensor and calculated.	Same
Design principle	Based on Infrared Sensor technology	Based on Infrared Sensor technology	Same
Sensor Type	Infrared sensor	Infrared sensor	Same
Measurement Range	32.0°C 42.9°C C89.6°F~109.2°F)	32.0°C 42.9°C (89.6°F~109.2°F)	Same
Accuracy for body temperature measurement	32.0°C~34.9°C: ±0.3°C / 0.5°F 35.0°C~42.0°C: ±0.2°C / 0.4°F 42.1°C~42.9°C: ±0.3°C / 0.5°F	32.0°C~34.9°C: ±0.3°C / 0.5°F 35.0°C~42.0°C: ±0.2°C / 0.4°F 42.1°C~42.9°C: ±0.3°C / 0.5°F	Same
Resolution of Display	0.1°C/°F	0.1°C/°F	Same
Operating Environment	15°C ~ 35°C 15%~85% moisture condensation	15°C ~ 35°C 85% moisture condensation	Different [3]
Storage Environment	-25°C~55°C C-4°F~131°F) 10%~90% moisture condensation	-20°C~55°C C-4°F~131°F) 90% moisture condensation	

Power supply	2*1.5V de AAA battery	2*1.5V de AAA battery	Same
Applicable standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO80601-2-56	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO80601-2-56	Same
Memory records	10 sets	20 sets	Different [4]
Product configuration	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	Same
Temperature unit and conversion	Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically	Dual temperature units "°C" and "°F" optional and the two units can convert by the conversion key automatically	Same
Physical Dimension	145mm * 37mm*35mm	30mm * 44mm *152mm	Different [5]
Weight	53 g(Including batteries)	About 72 g(without battery)	
Device Materials of the main unit	ABS	ABS	Same
Patient contact material	ABS	ABS+PE	Different [6]
Bio-compatibility Complied standards	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	Same
Display screen	LCD	LED	Different [7]
Sound from the device with successful measurement	When the measurement is complete, the result will show on the display screen after one long beep	When the measurement is complete, the result will show on the display screen after short beeps	

Justification for the differences:

1) Different Indications for Use and Intended patient population

The predicate and subject device share similar indications for use as shown in their labeling, and the difference is the subject is for people of all ages except neonates/newborns, while the predicate can only be used for people over three months. This difference has been verified by internal verification and an external clinical accuracy study, so this difference will not cause any safety or effectiveness problem.

2) Different Measuring Distance for forehead mode

The predicate device is contacting type for forehead mode, but the subject device is non-contact type. The software and hardware for the subject device is verified to be supportive of the safety and performance declared in the labeling, which will not cause any safety or effectiveness problem.

3) Different Operating/Transport conditions

Minor difference to operation/transport environment for the subject device, but the system has been

proven to be safe and effective based on the safety testing conducted under the suggested environment. Environment testing data shows the device can function as intended under the suggested conditions. So those changes will not cause any safety or effectiveness problem.

4) Different Memory Data Limit
The subject KFT series thermometer can store 10 sets of data less than the predicate, which is verified through device testing.

5) Different Patient contact material
The patient contacting materials of the predicate and the subject devices are ABS+PE and ABS, respectively. Both are compliant with international standards ISO 10993-5/ISO10993-10, and the corresponding test reports provided demonstrate material safety.

6) Different Physical Dimension and weight
The dimension and weight of the subject device are different from the predicate device. The physical characteristics differences have been verified during the design and development and will not raise any safety or effectiveness problem .

7) Different display screen and Sound from the device with successful measurement
The predicate and subject device differs in nonessential characteristics. The differences have been verified before product release, including hardware and software. No safety or effectiveness problem observed.

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, including appearance, control keys, and operating/storage environment, which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the KFT series Infrared thermometer system.

8. Performance Data

Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the **KFT** series Infrared thermometer were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. The testing necessary for this contact category include Cytotoxicity, Skin Sensitization and Irritation per the *Annex A Biological evaluation tests* of ISO 10993-1, which have been conducted on the IT series Infrared thermometer device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the KFT series Infrared thermometer device, consisting of all the modules and accessories in the system. The system complies with the ANSI/AAMI ES60601-1:2005/(R)2012and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the IEC 60601-1-2: 2014 *Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests* standard for EMC.

Bench Testing

Bench testing was conducted on the KFT series Infrared thermometer device, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2015 *MEDICAL ELECTRICAL EQUIPMENT -Part 1-11: General requirements for basic safety and essential performance -Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment,* ISO 80601-2-56: 2009 *Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement* standards for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

Clinical testing is conducted per ISO 80601-2-56 Clause 201.102 Clinical Accuracy Validation, where 116 patients are included in the testing, and with grouping shown below. Both forehead and ear measurement modes are evaluated with accuracy results.

Age	Number of tested group	Febrile/ Non-febrile
1~3 month	17	6/11
3 months ~1 year	25	12/13
1~5 years	38	17/21
Above 5 years	36	13/23

Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a performance that is similar to the predicate device.

9. Conclusion

Based on the above considerations table, the Proposed Device, the KFT series Infrared thermometer is substantially equivalent to the predicate device EFT-16 series Infrared thermometer (K171214).