November 20, 2018

Kangfu Medical Equipment Factory
Mr. Zelong Cao
Quality Manager
No. 380 Ningkang East Road
Yueqing City, Zhejiang 325600
CHINA

Re: K182652
Trade/Device Name: COCET Digital Thermometer (Models: KFT-01/KFT-02/KFT-03/KFT-04/KFT-05/KFT-06/KFT-07/KFT-08/KFT-09/KFT-10)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 24, 2018
Received: September 24, 2018

Dear Mr. Zelong Cao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182652

Device Name
COCET Digital Thermometer (Models: KFT-01/KFT-02/KFT-03/KFT04/KFT-05/KFT-06/KFT-07/KFT-08/KFT-09/KFT-10)

Indications for Use *(Describe)*
COCET Digital Thermometer measures body temperature. This digital thermometer is used in the armpit (axillary) to take temperature measuring results. The device is for adult use.

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

[Refer to 21 CFR §807.92]

K182652

1. Submitted by:

Kangfu Medical Equipment Factory
No.380 Ningkang East Road, Yueqing City 325600 Zhejiang Province China
Phone: 086-577-55775583
E-mail: zelong_858@126.com
Contact Person: Zelong Cao
Date Prepared: November 16, 2018

2. Trade Name:

COCET Digital Thermometer (Models: KFT-01/ KFT-02/ KFT-03/ KFT-04/ KFT-05/ KFT-06/ KFT-07/ KFT-08/ KFT-09/ KFT-10)
Common Name: Clinical electronic thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Classification: Class II
Product Code: FLL

3. Predicate Device:

K120004, DIGITAL THERMOMETER (Models: YT301/ YT302/ YT303)
Manufacturer: CHINA (Shenyang) Med-land Imp/Exp Corp., Ltd.

4. Device Description:

COCET Digital Thermometer (Models: KFT-01/ KFT-02/ KFT-03/ KFT-04/ KFT-05/ KFT-06/ KFT-07/ KFT-08/ KFT-09/ KFT-10) is a hand-held electronic thermometer, it comprised of an electronic thermo resistor (thermistor) sensor connected to printed circuit board(PCB) with liquid crystal display(LCD) user readout. The outer material of thermometer is made of ABS and the measuring tip is stainless steel. The thermometer using a temperature sensor to output an electrical signal, and then converting the current signal into a liquid crystal digital display temperature. The thermometers are powered by LR41 battery. The battery can be replaced.

5. Indications for Use:

COCET Digital Thermometer measures body temperature. This digital thermometer is used in the armpit (axillary) to take temperature measuring results. The device is for adult use.

6. Predicate Device Comparison

Table 1 Predicate Product Comparisons - COCET Digital Thermometer Models: KFT-01/ KFT-02/ KFT-03/ KFT-04/ KFT-05/ KFT-06/ KFT-07/ KFT-08/ KFT-09/ KFT-10

Feature	Kangfu Medical Equipment Factory Models: KFT-01/ KFT-02/ KFT-03/ KFT-04/ KFT-05/ KFT-06/ KFT-07/ KFT-08/ KFT-09/ KFT-10	CHINA (Shenyang) Med-land Imp/Exp Corp.,Ltd YT301/ YT302/ YT303	**Discussion**
510(k) Number	K182652	K120004	
Indications for Use	COCET Digital Thermometer measures body temperature. This digital thermometer is used in the armpit (axillary) to take temperature measuring results. The device is for adult use.	The Digital Thermometer is used for the measurement and monitoring of human body temperature. Body temperature can be measured with the Digital Thermometer by oral, axillary (under the arm) and rectal methods. The device is for adult and pediatric use.	Different
thermometer type	under arm	oral, axillary (under the arm) and rectal.	Different
components	Electronic thermo resistor(thermistor) sensor Printed circuit board(PCB) Liquid crystal display(LCD) Outer Tip	Electronic thermo resistor(thermistor) sensor Printed circuit board(PCB) Liquid crystal display(LCD) Outer Tip	Same
principal of operation	Using a temperature sensor to output an electrical signal, and then converting the current signal into a liquid crystal digital display temperature	Using a temperature sensor to output an electrical signal, and then converting the current signal into a liquid crystal digital display temperature	Same
Temperature Measurement Technology	NTC Thermistor Resistance Technique	NTC Thermistor Resistance Technique	Same
Key Temperature Sensor	NTC Thermistor	NTC Thermistor	Same
Power requirements	1xLR41 battery Standard voltage 1.5V, termination voltage 0.9V. Discharge with 1KΩ discharge resistor, sustainable discharge for 670 hours. Working	1xLR41 battery	Same

	capacity 28mAh, weight 0.61g. Load resistance 22K		
Materials	ABS plastic cabinet (White and blue), Stainless steel	ABS plastic cabinet (White), Stainless steel	Different
Temperature range	32.0 ° C ~ 42.9 ° C (90℉-109.2 ℉)	32.0 ° C ~ 42.9 ° C (90℉-109.2℉)	Same
Accuracy	+/- 0.1 ℃(±0.2℉) from 35.5 ℃ to 42 ℃(95.9℉-107.6℉) +/- 0.2 ℃(±0.4℉) in the rest measuring range	+/- 0.1 ℃(±0.2℉) from 35.5 ℃ to 42 ℃(95.9℉-107.6℉) +/- 0.2 ℃(±0.4℉) in the rest measuring range	Same
Biocompatibility	Comply with ISO 10993-1 ISO10993-5 ISO 10993-10	Comply with ISO 10993-1 ISO10993-5 ISO 10993-10	Same
Voluntary standards for Clinical Electronic Thermometers	Comply with ISO 80601-2-56	Comply with ASTME1112-00	Different
Medical Electrical Safety and EMC	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Same

Discussion:

1. Indications for Use is different from the description of the contrasting device, the two devices are measuring human body temperature, the predicate device is used orally, axillary (under the arm) and rectal for adult and pediatric, our COCET Digital Thermometer is only used under arm for adult, the difference does not raise performance questions.

2. Thermometer type: Our product COCET Digital Thermometer is only used in the armpit, the predicated device can be used orally , axillary (under the arm) and rectal, the difference does not raise performance questions.

3. Materials: The ABS plastic cabinet of predicate device only has white color, COCET Digital Thermometer has two color white and blue. However, it is conformed with ISO 10993 series standard. It can be proved in the biocompatibility testing report. The difference does not raise performance questions.

4. Voluntary standards for Clinical Electronic Thermometers: Electronic Thermometer comply with ASTME1112-00 and COCET Digital Thermometer comply with The ISO 80601-2-56, the two standards were meets FDA guidelines. The difference does not raise performance questions.

Name	Model	principal of operation	Dimension	Materials

COCET DIGITAL THERMOMETER	KFT-01	This digital thermometer is used in the armpit (axillary) and using a temperature sensor to output an electrical signal, and then converting the current signal into a liquid crystal digital display temperature	124.5mm× 18mm× 9mm	ABS plastic cabinet (White code:WH), Stainless steel
COCET DIGITAL THERMOME	KFT-02	same	120mm× 16mm× 9.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-03	same	127mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-04	same	127.5mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-05	same	133mm× 27.5mm× 10mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-06	same	132mm× 20mm× 7.5mm	ABS plastic cabinet (White code:WH Blue code:BU),

				Stainless steel
COCET DIGITAL THERMOME	KFT-07	same	127mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-08	same	127.5mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-09	same	127mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel
COCET DIGITAL THERMOME	KFT-10	same	127.5mm× 19mm× 11.5mm	ABS plastic cabinet (White code:WH Blue code:BU), Stainless steel

7. Non-clinical Tests

Safety and EMC:

Safety and EMC test was performed in according to the

- IEC 60601-1:2005+CORR.1:2006+CORR.2.2007+a1:2012
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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

Biocompatibility:

Biocompatibility testing was performed to evaluate the biocompatibility of the contact materials in accordance with ISO 10993-1:2009, the device passed each biocompatibility test identified below:

- Cytotoxicity testing in according to ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Skin irritation testing in according to ISO 10993-10:2010 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- Sensitization testing in according to ISO 10993-10:2010 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity

Performance Data:

The following bench testing was conducted in order to support substantial equivalence:

- ISO 80601-2-56:2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

8. Conclusion

Based on performance testing and compliance with voluntary standards demonstrate that the proposed device is substantially equivalent to the predicate device.