DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 24, 2016

Hangzhou Universal Electronic Co., Ltd.
c/o Mr. Charlie Mack
IRC
7808 Rush Creek Drive
Pasco, Washington 99301

Re: K160802
Trade/Device Name: Infrared Forehead Thermometer, FT-100A
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 16, 2016
Received: July 20, 2016

Dear Mr. Mack:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160802

Device Name
Infrared forehead thermometer, FT-100A

Indications for Use *(Describe)*
The FT-100A Electronic thermometer is an Infrared thermometer which uses an infrared sensor to detect human body temperature of patients of all ages. It is intended to be used on forehead to detect body temperature. The FT-100A is intended for home 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K160802

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

Date: March 5, 2016

1. Company and Correspondent making the submission:

Name – Hangzhou Universal Electronic Co., Ltd.
Address – 38 Yangjiatang, Sandun, Westlake District, Hangzhou City Zhejiang Province, China 310030
Tel: 86-755-86213939
Fax: 86-571-89905288
Contact – Mr. Jiaqiang Wan
General Manager
Email – charliemack@irc-us.com

2. Device :

Trade/proprietary name: FT-100a
Common Name : Clinical electronic thermometer
Classification Name : thermometer, electronic, clinical

3. Predicate Devices :

Manufacturer	Predicate Device	510(k) Number	Submitted Device
TaiDoc Technology Corporation	NEXUS IR30 NON-CONTACT INFRARED FOREHEAD THERMOMETER	K122221	Infrared Forehead Thermometer, FT-100A

4. Classifications Names & Citations :

21CFR 880.2910, FLL, Clinical electronic thermometer

5. Description :
The Universal Infrared Forehead Thermometer, Model FT-100A is a non-contact thermometer which infers temperature from the blackbody radiation emitted from the patient. Temperature is calculated from the knowledge of the amount of infrared energy emitted from the human body.

The design consists of a lens to focus the infrared thermal radiation on to a detector, which converts the radiant power to an electrical signal that can be displayed in units of temperature after being compensated for ambient temperature. This permits temperature measurement from a distance without contact with the object to be measured.

There are some specific limitations to the use of the FT-100A.

It is suggested that a control measurement using a conventional thermometer is recommended in the following cases if the reading is surprisingly low, for new-born infants up to 100 days old or for children under three years of age who have a weakened immune system or who react unusually in the presence or absence of fever

6. Indication for use:
The FT-100A Electronic thermometer is an Infrared thermometer which uses an infrared sensor to detect human body temperature of patients of all ages. It is intended to be used on forehead to detect body temperature. The FT-100A is intended for home use.

7. Comparison with predicate device:
Hangzhou Universal Electronic Co., Ltd. believes that the Infrared Forehead Thermometer, FT-100A is substantially equivalent to the (K122221) Nexus Ir30 Non-Contact Infrared Forehead Thermometer (TaiDoc Technology Corporation).

There are differences between the Indications For Use between the predicate TaiDoc Technology Corporation device and the submitted Hangzhou FT-100A device. The difference is simply different grammatical approaches to state that the same point. Both Indication For Use statements state the intended use is to take body temperature from an Infrared device on the same patient population in the same environment.

Content	New Device	Predict Device
Device Name	Infrared forehead thermometer, FT-100A	Nexus IR30 Thermometer (TD-1265)
Manufacturer	Hangzhou Universal Electronic Co., Ltd.	TaiDoc Technology Corporation
510(K)	N/A	K122221
Indication for Use	The FT-100A Electronic thermometer is an Infrared thermometer which uses an infrared sensor to detect human body temperature of patients of all ages. It is intended to be used on forehead to detect body temperature. The FT-100A is intended for home use.	Nexus IR30 Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the surface of human skin without contact. It is for use on people of all ages (infants, children, adolescents, and adults) in the homecare environment.
Temperature unit	Same	℃ or ℉
Measurement range	Same	Forehead: 32.0°C to 43.0°C (89.6°F to 109.4°F) Object: 0°C to 100°C (32°F to 212°F)
Operating temperature	Same	16°C to 40°C (60.8°F to 104°F)
Operating humidity	85% RH or less	95% RH or less
Storage temperature	Same	-25°C to 55°C (-13°F to 131°F)
Storage humidity	Same	95% RH or less
Accuracy	FOR BODY MODE: Same as predict device ± 0.2°C (±0.4°F) from 36.0°C (96.8°F) to 39.0°C (102.2°F) ± 0.3°C (±0.5°F) from 32.0°C (89.6°F) to 35.9°C (96.6°F) and from 39.1°C (102.4°F) to 43.0°C (109.4°F) FOR OBJECT MODE: ± 4°C (±7.2°F) from 0°C (32°F) to 4.9°C (40.8°F) ± 1°C (±2°F) from 5.0°C (32°F) to 60.0°C (140.0°F) ± 4°C (±7.2°F) from 60.1°C (140.1°F) to 100°C (199.9°F)	FOR BODY MODE: ±0.2°C (±0.36°F) from 36.0°C (96.8°F) to 39.0°C (102.2°F) ±0.3°C (±0.54°F) from 32.0°C (89.6°F) to 35.9°C (96.6°F) and from 39.1°C (102.4°F) to 43.0°C (109.4°F) FOR OBJECT MODE: ± 1°C (±2°F) from 0°C (32°F) to 100°C (212°F)
Memory capacity	Same	20 measurements
Power down time	1 min	15 seconds
Battery type	1.5V AAA×2	1.5V AAA x 2
LCD Backlight	Available	Available
Fundamental scientific technology	Infrared technology	Infrared technology
Display resolution	0.1˚C/0.1 ˚F	0.1˚C/0.1 ˚F

8. Safety and Performance Data:

Test Report File No.	Test	Standards	Result
SDWH-M201502527-1	In vitro cytotoxicity with 10% FBS	ISO 10993-5:2009	Pass
SDWH-M201502527-2	Skin sensitization 0.9%SC	ISO 10993-10:2010	Pass
SDWH-M201502527-3	Skin sensitization sesame oil	ISO 10993-10:2010	Pass
SDWH-M201502527-4	Skin irritation 0.9%SC	ISO 10993-10:2010	Pass
SDWH-M201502527-5	Skin irritation sesame oil	ISO 10993-10:2010	Pass
			Pass
EED33H000003-2	General requirements for basic safety and essential performance	ANSI/AAMI ES60601-1: 2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012	Pass
EED32H000003	EMC TEST	IEC 60601-1-2:2007	Pass
GF20150815001	Particular requirement for basic safety and essential performance of clinical thermometers for body temperature Measurement	ISO 80601-2-56:2009	Pass
GF20150518001	Standard specification for infrared thermometers for intermittent determination of patient temperature	ASTM E1965-98(Reapproved 2009)	Pass

9. Clinical: A clinical investigation was performed to evaluate the clinical accuracy and clinical repeatability on the following three age groups: 0-12 months, 12 months- <5 years, and 5 years and older in accordance with ASTM E1965-98 (Reapproved 2009) to compare the Infrared Forehead Thermometer, FT-100A (test thermometer) with the predicate Nexus IR30 Thermometer (TD-1265) (K122221).

   This clinical investigation demonstrated that the Infrared Forehead Thermometer, FT-100A is as safe and effective as predicate device, Nexus IR30 Thermometer, TD-1265 (K122221) in all age groups with respect to the bias and standard deviation in comparison to the Reference SureTemp Plus Oral/Rectal and Axillary Contact Thermometer in the monitoring mode (K030580). The temperatures obtained with the test Infrared Forehead Thermometer were equivalent when compared to the predicate device, where temperatures were measured in the oral mode (for children above 5 years) and axillary mode (for children under 5 years). The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM E1965-98 (Reapproved 2009) standard were within clinical acceptability (bias less than predicate device when compared to reference). The clinical repeatability of the Infrared Forehead Thermometer, FT-100A was statistically and clinically acceptable (less than 0.3 deg C or 0.58 deg F).

   The design of the submitted device specifications is substantially the same as the predicate, with minor differences in the storage humidity range.

   All the labeling and characteristics of the submitted OTC Infrared Forehead Thermometer, FT-100A are the same as the predicate devices and most typical OTC Infrared Forehead Thermometers currently on the market. The submitted device and predicate both are used for measuring patient temperatures and also to measure object temperatures.

10. Conclusions:

    In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Hangzhou Universal Electronic Co., Ltd. concludes that the Infrared Forehead Thermometer, FT-100A are substantially equivalent to predicate devices as described herein.

11. Hangzhou Universal Electronic Co., Ltd. will update and include in a summary any other information deemed seasonably necessary by the FDA.

END