May 17, 2018

Shenzhen Jiacom Technology Co., Ltd
% Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K172894
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 16, 2018
Received: April 18, 2018

Dear Diana Hong:

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.

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.

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, 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)*
K172894

Device Name
Infrared Thermometer

Indications for Use *(Describe)*
Infrared Thermometer is intended to detect body temperature from the forehead or auditory canal in the population including infant (above 6 months), child, adolescent, and adult

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

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172894

1. Date of Preparation: 5/14/2018

2. Sponsor Identification

Shenzhen Jiacom Technology Co ., Ltd
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Betty Xiao (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Infrared Thermometer
Common Name: Clinical electronic thermometer
Model: IFR 600

Regulatory Information
Classification Name: Clinical electronic thermometer
Classification: Class II
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Review Panel: General Hospital

Indication for Use Statement:
Infrared Thermometer is intended to detect body temperature from the forehead or auditory canal in the population including infant (above 6 months), child, adolescent, and adult.

Device Description

The proposed device, Infrared Thermometers IFR 600 is hand-held, reusable, battery powered device, which is intended to detect body temperature from forehead or auditory canal in the pediatric and adult population.

IFR 600 infrared thermometer can measure human body temperature by both ear and forehead measurement.

5. Identification of Predicate Device(s)

510(k) Number: K111463
Product Name: Valeo VT-601 Series ZR Thermometer

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

- AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012, c1:2009/(R)2012 and A2:2010/(R)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 Compatibility - Requirements And Tests.
- ISO 80601-2-56 First Edition 2009-10-01, Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
- ASTM E1965-98 (R 2016), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

The proposed device is tested to evaluate its electrical safety and electromagnetic compatibility. The test results demonstrated that the proposed device complies with the standards.

7. Clinical Test Conclusion

Controlled human clinical studies were conducted in accordance with ASTM E 1965-98(2003), clinical bias, clinical uncertainty and clinical repeatability have been evaluated per clinical validation for infrared thermometer .the clinical trial results verify that the clinical accuracy of the proposed device is not inferior to that of predicate device.

40 of each age range of subjects are included in the clinical studies, the amounts of male subjects are the same with that of female subjects, and 35%~37.5% of total subjects are febrile person. Compared statistical result of clinical bias and clinical repeatability of two comparison groups, the result of proposed device is not being inferior to that of predicate device. The result of proposed device was not inferior to that of predicate device, and the proposed device complies with ASTM E1965-98.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed device	Predicate Device K111463
Product Code	FLL	FLL
Regulation Number	21 CFR 880.2910	21 CFR 880.2910
Indications for Use	Infrared Thermometer is intended to detect body temperature from the forehead or auditory canal in the	The Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D, VT-601E, VT-601F) is infrared thermometers intended for the intermittent measurement of human body

	population including infant (above 6 months), child, adolescent, and adult.		temperature in people of all ages.	
Measurement Site	Forehead and eardrum		Forehead and eardrum	
Principle of Operation	Non-contacting, Infrared Temperature Measurement		Non-contacting, Infrared Temperature Measurement	
Ear Mode				
Range	32.0℃-42.9℃		32.0℃-42.9℃	
Accuracy	±0.2℃ at 35.5℃-42.0℃ ±0.3℃ at 32.0-35.0℃ and 42.0℃-42.9℃		±0.2℃ at 36.0℃-39.0℃ Others ±0.3℃	
Forehead Mode				
Range	34. 0℃-42.9℃		22.0℃-42.2℃	
Accuracy	±0.2℃ at 35.5℃-42.0℃ ±0.3℃ at 34.0-35.4℃ and 42.1℃-42.9℃		±0.3℃ at 22.0℃-40.0℃	
Display type	LCD		LCD	
Activation	Scan button		Scan button	
Power requirements	3Vdc		3Vdc.	
Material	Enclosure and key: ABS (Acrylonitrile Butadiene Styrene) Color additive: Titanium dioxide and Phthalocyanine blue		Unknown	
Electrical Safety	Complied with IEC 60601-1		Complied with IEC 60601-1	
EMC	Complied with IEC 60601-1-2		Complied with IEC 60601-1-2	
Performance	Complied with ISO 80601-2-56		Complied with ISO 80601-2-56	
	Complied with ASTM E1965 -98 (2003)		Complied with ASTM E1965 -98 (2003)	
Biocompatibility	Cytotoxicity	Complied with ISO 10993-5	Cytotoxicity	Complied with ISO 10993-5
	Irritation	Complied with ISO 10993-10	Irritation	Complied with ISO 10993-10
	Sensitization	Complied	Sensitization	Complied with ISO

		with ISO 10993-10		10993-10

The proposed device and predicate device have the same measurement site, principle of operation and power requirement. Although the measurement range and accuracy are different, they comply with ISO 80601-2-56 and ASTM E 1965-98(2006), thus the difference will not arise the issues related to safety and effectiveness. The materials of predicate are not known, however, the proposed device has been conducted cytotoxicity, irritation and sensitization to demonstrate its biocompatibility. And both the proposed device and predicate device are conducted electrical safety and EMC testing according to IEC 60601-1 and IEC 60601-1-2, the test result shows the proposed device meets the requirements of these standards. Therefore, the proposed device and predicate device can be considered as substantially equivalent.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.