February 18, 2021

Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
℅ Arthur Goddard
President
FDA Regulatory and Quality Systems Consultant
31853 Cedar Road
Mayfield Heights, Ohio 44124-4445

Re: K202687
Trade/Device Name: Infrared Forehead Thermometer, Model LFR30B, LFR50, LFR60
Regulation Number: 21 CFR 21 CFR 880.2910
Regulation Name: Clinical Electrical Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 3, 2020
Received: September 15, 2020

Dear Arthur Goddard:

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,

For 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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202687

Device Name
Infrared Forehead Thermometer, Model LFR30B, LFR50, LFR60

Indications for Use *(Describe)*
The Infrared Forehead Thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical 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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Section 5: 510(K) Summary

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

The assigned 510(K) Number: K202687

5. 510(K) Summary

5.1. Date of Preparation: February 18, 2021

5.2. Sponsor

Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
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Contact Person: Aaron Lin
Position: General Manager
Email: aaron.lin@lepu-medical.com

5.3. Subject Device Identification

Subject Device Name: Infrared Forehead Thermometer, Model LFR30B, LFR50, LFR60
Common name: Infrared Forehead Thermometer
Regulation Name: Clinical Electronic Thermometer
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Review Panel: General Hospital
Classification: II

5.4. Predicate Device

510(k) Number: K191251
Device Name: Infrared Thermometer (DT-8836T, DT-8836P)
Manufacturer: Shenzhen Calibeur Industries Co., Ltd.

5.5. Indications for use:

The Infrared Forehead Thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.

5.6. Device Description

The subject device Infrared Forehead Thermometer has three models: LFR30B, LFR50 and LFR60. The three modes have same operation principle. A thermopile sensor is employed to detect the infrared energy emitted from the surface of the skin of the forehead which is converted into temperature measurement with the unit of °C or °F. The results can be displayed on LCD. The measurement is non-contact with the patient. The measuring distance is 0~5 cm to the forehead and the measuring time is 1s. The Infrared Forehead Thermometer is battery powered.

5.7. Predicate Devices and Subject Device Comparison

Item	Subject Device Infrared Forehead Thermometer	Predicate Device Infrared Thermometer (DT-8836T, DT-8836P) K191251	Remark
Device Common/Usual Name	Infrared Forehead Thermometer	Infrared Thermometer	/
Device Class	Class II	Class II	SE
Product Code/ Regulation Number	FLL 21 CFR 880.2910	FLL 21 CFR 880.2910	SE
Classification Name(s)	Clinical Electronic Thermometer	Clinical Electronic Thermometer	SE
Indications for Use	The Infrared Forehead Thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	The Infrared thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	SE
Intended Users	Lay user and professional	Lay user and professional	SE
Measurement Method	Infrared radiation detection	Infrared radiation detection	SE
Measuring Site	Forehead	Forehead	SE

Item	Subject Device Infrared Forehead Thermometer	Predicate Device Infrared Thermometer (DT-8836T, DT-8836P) K191251	Remark
Scale Selection	°C/°F	°C/°F	SE
Measuring Range	32-43°C/89.6-109.4°F	32.0°C ~42.5°C (89.6 to 108.5 °F)	Discussion 1
Discussion 1： The measuring range of subject device is different with predicate device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Display Resolution	0.1°C/0.1°F	0.1°C/0.1°F	SE
Measuring Accuracy	±0.3°C (±0.5°F) within 34.0~43°C (93.2~109.4°F), ±0.4°C (±0.7°F) within 32.0~33.9°C (89.6~93.0°F)	±0.2°C (0.4°F) within 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F), ±0.3°C(0.5°F) other range	Discussion 2
Discussion 2： The measuring accuracy of subject device is different with predicate device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E 1965. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Measure Time	1s	1s	SE
Measure Distance	0~5cm	≤3cm	Discussion 3
Discussion 3： The measure distance of subject device is different with predicate device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E 1965. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Sensor	Thermopile	Thermopile	SE
Audio Reminder	Buzzer	Buzzer	SE
Data Storage	Up to 99 sets	60 sets	Discussion 4
Discussion 4： The data storage of subject device is different with predicate device. However, the software was validation according to FDA's software guidance. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E 1965. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Power Supply	Battery	Battery	SE
Display Screen	LCD	LCD	SE

Item	Subject Device Infrared Forehead Thermometer	Predicate Device Infrared Thermometer (DT-8836T, DT-8836P) K191251	Remark
Operating Condition	5°C~40°C, Relative Humidity 24~90%	10~40°C (50°F ~104 °F) RH 15~95%	Discussion 5
Storage/transport Condition	-20°C~+55°C, Relative Humidity < 95%	-25 ~+55°C (-13~+131°F) RH:15~95%	
Discussion 5: The operating and storage/transport condition of subject device are different with predicate device. The performance testing shows that the subject device complies with performance standard IEC 80601-2-56 and ASTM E 1965. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Human-contacting Material	ABS, PC, PMMA	ABS	Discussion 6
Discussion 6: The human-contacting material of subject device is different with predicate device. PC and PMMA are widely used in medical device. The biocompatibility evaluation of the subject device was conducted according to FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Cytotoxicity, sensitization and irritation tests are performed. The test reports addressed during the biocompatibility studies (Section 15: Biocompatibility) did not raise any new issues of biocompatible safety. The difference with predicate device K191251 doesn't raise any new issues of safety or efficacy.			
Biocompatibility Information	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	SE
Reference Body Site	Axilla	Axilla	SE
Measuring Mode	Adjusted (Body mode)	Adjusted (Forehead mode)	SE
Conformance Standard	ISO 80601-2-56 IEC 60601-1 IEC 60601-1-2 ASTM E1965	ISO 80601-2-56 IEC 60601-1 IEC 60601-1-2 ASTM E1965	SE

5.8. Performance Test Summary

Bench test were conducted to verify that the subject device met all design specifications, as was Substantially Equivalent (SE) to the predicate device.

5.8.1. Biocompatibility Testing

The Infrared Forehead Thermometer was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The subject device would be classified as a Surface Medical Device in contact with the intact skin for a Limited Duration (<24 hours). The following test were performed for any user contacting material:

Test	Standard	Results
In Vitro Cytotoxicity Study (MTT Method)	ISO 10993-5	Under the conditions of this study, the MEM test extracts would be considered no cytotoxicity potential. The negative controls, blank controls, and the positive controls performed as anticipated.
Skin Sensitization Study Guinea Pig Maximization Test	ISO 10993-10	Under the conditions of this study, the test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
Skin Irritation Study	ISO 10993-10	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.

5.8.2. Non-clinical Tests

The Infrared Forehead Thermometer is tested per the following standard, to evaluate its performance. The test results demonstrated that the proposed device comply with the standard requirements.

IEC 60601-1:2005+AMD1:2012 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

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 80601-2-56:2017+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.

ASTM E1965-98 (2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

5.8.3. Clinical Data

A comparison study and clinical repeatability testing was performed on the following four age groups: 0 up to 3 months, 3 months up to 1 year, older than 1 year and younger than 5 years and older than 5 years in accordance with ISO 80601-2-56 to compare the Infrared Forehead Thermometer with Mercury thermometer. This clinical comparison study demonstrated that the temperatures obtained with the Infrared Forehead Thermometer were highly related when compared to the Mercury thermometer, the clinical bias with stated uncertainty and clinical repeatability as defined in the ISO 80601-2-56 standard were within clinical acceptability.

5.8.4. Software

The software embedded in Infrared Forehead Thermometer has been developed, documented and validated in accordance with industry standards (IEC 62304 – Medical device software – Software life cycle processes) and FDA guidance (GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES).

5.9. Substantially Equivalent Conclusion

The subject device, Infrared Forehead Thermometer, is determined to be Substantially Equivalent (SE) to the predicate device, K191251, in respect of safety and effectiveness.