DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 21, 2016

Nexmed Technology Co., Ltd
c/o Ms. Elena Lu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122, International Mayors Communication Centre
Shenzhen, 518101
CHINA

Re: K160816
Trade/Device Name: Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 15, 2016
Received: August 22, 2016

Dear Ms. Elena Lu:

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)*
K160816

Device Name
Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)

Indications for Use *(Describe)*
Infrared Thermometer is intended for body temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

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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VOL 05 510(k) Summary

K160816

5.1 Administrative Information

Date of Summary prepared	Aug., 31, 2016
Manufacturer information	Nexmed Technology Co., Ltd. 2 Floor Of No.1 Building, Jia An Technological Industrial Park, 67 District, Bao An, Shenzhen, Guangdong, China 518101 Contact person: Ellen Xu Phone: +86-755-2948 1701 Fax: +86-755-8525 8461 E-mail: ellen@nxm-tech.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: Room 2032, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Ms. Elena Lu; Mr. Field Fu E-Mail: elena@cefda.com; cefda13485@163.com
Establishment registration number	

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Infrared Thermometer
Model:	LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10
Classification name:	thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL

Device Class:	II
Regulation Number:	880.2910

5.3 Predicate Device Information

Sponsor:	Shenzhen Jumper Medical Equipment Co., Ltd.
Device:	Non-contact Infrared Thermometer
510(K) Number:	K131243

5.4 Device Description

The subject device uses infrared probe to detect the radiated infrared energy emitted by the object, solid, liquid or gas. The intensity of the emitted energy depends on the temperature of the object. The infrared probe (Thermopile) can recognize it and transfer to the proper electronic signal. The electronic signal can be processed in the Infrared Thermometer to convert to the temperature reading, which is displayed on the LCD. Therefore, the subject device is able to measure the temperature of a person by the energy the person emits.

The subject device intends to detect the temperature of patients of all ages.

The subject device includes 2 series: ThermoFlash and MyThermo. The ThermoFlash thermometers contain 5 models: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, while MyThermo thermometer contains one model BW-CX10. They all have the following basic functions:

- Sound alarm if temperature is exceeded.
- LCD back-lighted digital screen.
- Data displayed in Celsius or Fahrenheit.
- Automatic stop (energy saver).
- Small, convenient, easy to use.

Their differences are in appearance and functions. The LX-26E and LX-360 are same in functions, while LX-260TE and LX-361T contain additional language function, BW-CX10 and PRO LX-261E contain additional rechargeable function, and BW-CX10 contains additional Bluetooth function.

5.5 Intended Use/ Indications for Use

Infrared Thermometer is intended for body temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

5.6 Technological characteristics of the subject device compared to the predicate device

Items	Predicate Device (K131243), Jumper	Subject Device	Remarks
Indications for use	The non-contact infrared thermometer, model JPD-FR100, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.	Infrared Thermometer is intended for body temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Measurement mode	Forehead measure mode	Body mode, also is forehead measurement mode	Same
Measuring range	Forehead temperature mode: 32.2℃ - 43.3℃ (90.0℉ - 109.9℉)	Body mode: 30℃to 43℃ (86.0℉ to 109.4℉)	Similar
Display resolution	0.1℃ (0.1℉)	0.1℃/0.1℉	Same
C/F switchable	Yes	Yes	Same
Measuring accuracy	Forehead temperature mode: ±0.2℃ (0.4℉)	+/- 0.2℃ in Body mode	Same
Display	LCD display	LCD display	Same
Measurement distance	1-6cm	2-5cm	Similar

Items	Predicate Device (K131243), Jumper	Subject Device	Remarks
Memory	20 sets	LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T: 32 sets; BW-CX10: It does not memory any data, and the data are transferred to the mobile phone app for memory.	Similar
Power source	Two 1 .5V AAA batteries	LX-26E, LX-260TE: two 1.5V AA batteries; LX-360, LX-361T: two 1.5V AAA batteries; PRO LX-261E, BW-CX10: 3.7V Lithium battery	Different (**Note 01**)
Low battery indication	Yes	Yes	Same
Waterproof	No	No, IP22	Different (**Note 02**)
Dimension	145 x 60 x 50mm	LX-26E: 102.5mm×42.3mm×155mm LX-260TE: 102mm×38mm×160.8mm PRO LX-261E: 102.5mm×38mm×158mm (without base) 156mm×66.6mm×177mm (with base) LX-360, LX-361T: 162.5mm×59mm×29.8mm (without base) 172.5mm×60.35mm×60.35 mm (with base) BW-CX10: 60.7 x 37.4 x 96.3 mm	Different (**Note 03**)

Items	Predicate Device (K131243), Jumper	Subject Device	Remarks
Weight	180g	LX-26E: 177g (with battery) 130.2g (without battery) LX-260TE: 179.4g (with batteries) 132.6g (without battery) PRO LX-261E: 193.2g (without base) 406.6g (with base) LX-360, LX-361T: 135g with base and battery 112g with base no battery 97g without battery or base BX-CX10: 177g (with battery)	Different (**Note 03**)
Operating condition	10℃ -40℃, <95%RH, no-condensing	15℃ ~ 40℃ 10%RH ~ 85%RH	Similar
Bluetooth	No	LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T: No BW-CX10: Yes	Different (**Note 04**)
Patient contact materials	ABS and TPE	ABS with colorants (yellow, green, blue, dark blue, aqua, purple and white) and PC	Different (**Note 05**)
Cleaning	The probe tip and lens are cleaned and disinfected by 70° alcohol.	The probe tip and protective glass over the lens are cleaned and disinfected by 70°alcohol.	Similar
Biocompatibility	Comply with ISO 10993-5:2009, ISO 10993-10:2010	Comply with ISO 10993-5: 2009, ISO 10993-10: 2010	Similar
Electric Safety and EMC	lEC 60601-1: 1988+A1:1991+A2:1995, lEC 60601-1-2: 2007, IEC 60601-1-11:2010	IEC 60601-1: 2005+CORR.1 (2006)+CORR.2 (2007), lEC 60601-1-2: 2007, IEC 60601-1-11: 2010, ISO 80601-2-56: 2009.	Similar

Items	Predicate Device (K131243), Jumper	Subject Device	Remarks
Performance	ASTM E1965-98 (2009)	ASTM E1965-98 (2009), ISO 80601-2-56: 2009.	Similar

Note 01:
PRO LX-261E and BW-CX10 have passed over charge tests, IEC 62133 tests and UN38.3 tests.

Note 02:
The subject devices have passed IEC 60601-1 and IEC 60601-1-11 safety test.

Note 03:
The subject devices have passed IEC 60601-1, IEC 60601-1-11 safety test, IEC 60601-1-2 EMC test and ISO 80601-2-56 performance test.

Note 04:
BW-CX10 has passed 47 CFR PART 15 Subpart B, 47 CFR PART 15 Subpart C and EN 300328 Tests.

Note 05:
The patient contact materials had passed the Biocompatibility Test.

The subject device and the predicate device have the same intended use and similar technological characteristics, they both use infrared radiation detection method to detect human body forehead temperature. Their design is compact, small and light-weight. They are same in measuring accuracy, and similar in measuring range. For the subject device, the model BW-CX10 contains Bluetooth function. However, information contained in this submission demonstrates that any differences in their characteristics do not raise any new questions. Thus, the subject device is substantially equivalent to the predicate devices.

5.7 Brief discussion of the nonclinical tests

The nonclinical tests of the Infrared Thermometer are listed as below table:

Tests	Test Standards	Results
Electric Safety	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
EMC	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; 47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators	Pass
Electric Safety for medical device used in the home healthcare environment	IEC 60601-1-11 Edition 1.0 2010-04, 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	Pass
Basic Safety and essential performance of clinical thermometers for body temperature measurement	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	Pass
Clinical accuracy	ASTM E1965-98 (Reapproved 2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	Pass
Biological Evaluation	ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Pass
In vitro	ISO 10993-5:2009, Biological evaluation of	Pass

Tests	Test Standards	Results
Cytotoxicity	medical devices - Part 5: Tests for *in vitro* cytotoxicity	
irritation and skin sensitization	ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
Battery Safety	IEC 62133 Edition 2.0 2012-12, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	Pass
Battery transportation Safety	UN 38.3, the Fifth Revised Edition Amendment 2 of the Recommendations on the Transport of Dangerous Goods, Manual of Test and Criteria (ST/SG/AC.10/11/Rev.5/Amend.2/Section 38.3)	Pass
QoS testing	47 CFR PART 15 Subpart B, Radio Frequency Devices Subpart B – Unintentional Radiators; 47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators	Pass
Wireless coexistence	47 CFR PART 15 Subpart B, Radio Frequency Devices Subpart B – Unintentional Radiators; 47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators; EN 300328 V1.8.1, Electromagnetic compatibility and Radio spectrum Matters(ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive	Pass

5.8 Brief discussion of clinical tests

The clinical performance test protocol and data analysis followed the requirements of ASTM E1965-98 (2009). The test report showed the clinical performance of subject device complied with the requirements of ASTM E1965-98 (2009). It is acceptable to measure patient's temperature.

5.9 Conclusions

Based on the above information, we conclude the subject device, Infrared Thermometer, is substantially equivalent to the predicate device.