



Food and Drug Administration
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November 17, 2016

Shenzhen Dongdixin Technology Co., Ltd.
Siping Yuan
R.A. Specialist
No. 3 Building Xilibaimang Xusheng Industrial Estate
Nanshan, Shenzhen, 518108
CHINA

Re: K161735
Trade/Device Name: Non-contact Forehead Thermometer TH1009N
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 11, 2016
Received: October 13, 2016

Dear Siping Yuan:

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,

 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

Indications for Use

510(k) Number (if known)

K161735

Device Name

Non-contact Forehead Thermometer TH1009N

Indications for Use (Describe)

The Non-contact Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the centre of the forehead as the measurement site on people of all ages.

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

K161735

Non-contact Forehead Thermometer

Date of Prepared: 06/17/2016
Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd
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This 510(K) Summary of information is being submitted in accordance with requirements of Title 21 CFR Section 807.92.

1. Proposed Device:

- 1.1. Device Trade Name:** Non-contact Forehead Thermometer TH1009N
- 1.2. Regulation numbers and common names:** 21 CFR 880.2910 Clinical electronic thermometer
- 1.3. Classification:** Class II
- 1.4. Product Code:** FLL

2. Predicate Device:

Legally Marketed Device: NTF 3000 No Touch+Forehead Thermometer

510(k) Number: K134043

Submitter: Kaz USA, Incorporated

3. Description of Proposed Device:

The Non-contact Forehead Thermometer (Model TH1009N) is a hand-held, battery powered device designed to measure human body temperature. The TH1009N is a kind of medical device that utilize infrared radiation to measure body temperature. The Non-contact Forehead Thermometer is intended to measure forehead temperature.

The Non-contact Forehead Thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, and an infrared distance sensor for detection of contact or non-contact (at a distance of approximately 0-5cm) use and compensation of the temperature reading.

4. Indications for Use

The Non-contact Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.

5. Technical and Performance Comparison

The following table compares the device to the predicate device with basic technological characteristics.

Items	Subject device	Predicate device	Discussion
510K#	K161735	K134043	N/A
Classification	Clinical Electronic thermometer Class II 21 CFR 880.2910	Clinical Electronic thermometer Class II 21 CFR 880.2910	Same
Device Name	Non-contact Forehead Thermometer TH1009N	NTF 3000 No Touch+Forehead Thermometer	N/A
Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Kaz USA, Incorporated	N/A
Indications for use	The Non-contact Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the centre of the forehead as the measurement site on people of all ages.	The No Touch + Forehead Thermometer(Model NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the centre of the forehead as the measurement site on people of all ages.	Same
Target Population	People all ages	People all ages	Same
Components	Enclosure, Sensor, CPU, LCD	Enclosure, Sensor, CPU, LCD, Protective cap	Different
Principle of operation	Infrared Sensor technology	Infrared Sensor technology	Same
Material	ABS	ABS	Same
Measure site	Forehead	Forehead	Same
Measure distance	0-5 cm	0-5 cm	Same
Unit of measurement	°C/°F	°C/°F	Same
Body measuring range	32.0-42.9 °C (89.6-109.3 °F)	34.4 - 42.2 °C (93.9 -108 °F)	Different
Accuracy	±0.2 °C (0.4 °F) for 35.0 °C (95.0 °F)-42.0 °C (107.6 °F), ±0.3 °C (0.5 °F) for Other range	± 0.4 °F for the range 95 °-107.6 °F (± 0.2 °C for 35-42 °C)	Same
Ambient range	5.0 °C - 59.9 °C (41.0 °F-104 °F)	15 °C - 40 °C (59.0 °F-104.0 °F)	Different
Display type	LCD	LCD	Same
Power requirements	3V DC	3V DC	Same
Operating	15.0 °C - 40.0 °C (59.0 °F - 104.0 °F)	59 °F - 104 °F (15 °C - 40 °C)	Same

temperature	with a relative humidity of 15%~85%, Atmosphere pressure: 700hPa-1060hPa		
Storage and transport temperature	-20°C - 55°C (-4°F - 131°F) with a relative humidity of 15%~90%, Atmosphere pressure: 700hPa-1060hPa	-13 °F to 140 °F (-25 °C to 60 °C) Humidity: 15 - 95% non condensing, 700-1060hPA (0.7-1.06 atm)	Different

Discussion:

The following differences exist between the subject and predicate devices are as follows:

- Components – There is no sensor protective cap with subject device. The cap protects thermometer sensor from dust. However, when there is dust on the sensor, user can clean it according to user manual. So this difference has no effect on functionality of the thermometer.
- Body measuring range – The subject device has wider measurement temperature range than predicate device, the subject device complies to the standard ISO 80601-2-56 and ASTM E1965-98. This difference does not pose any new performance questions.
- Ambient range – The subject device has wider displayed room temperature range than predicate device, the subject device complies to the standard ISO 80601-2-56 and ASTM E1965-98. The software verification and validation test met the requirements of the standards. This difference does not pose any new performance questions.
- Storage and transport temperature – The subject device has wider storage and transport conditions, the subject device complies to the standard IEC 60601-1-11. This difference does not pose any new performance questions.

The similarities and differences described in the comparison table demonstrate that the Non-contact forehead thermometer TH1009N is substantially equivalent to predicate and does not raise new performance questions.

6. Non-clinical performance data

The following **non-clinical performance data** are provided in support of the substantial equivalence determination. Performance testing was conducted to validate and verify that Non-contact Forehead Thermometer, model TH1009N meets all requirements of related international standards, including electrical safety, EMC, biocompatibility, software validation and product cleaning. Results of these tests demonstrate compliance to the requirements of the below consensus standards.

Electrical Safety and performance requirements:

- IEC 60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- ISO 80601-2-56:2009 Medical electrical equipment Part 2-56 Particular requirements for basic

safety and essential performance of clinical thermometers for body temperature measurement

- ASTM E1965-98(Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2010 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

Electromagnetic compatibility requirements:

- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Biocompatibility Evaluation for patient contacting components:

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

Software Verification and Validation Testing:

In addition to the compliance of voluntary standards, Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern. IEC 62304 was followed.

7. Clinical testing data

Clinical evaluation of Non-contact Forehead Thermometer was conducted by Shenzhen Dongdixin Technology Co., Ltd in compliance with ASTM E1965-98(Reapproved 2009) Standard. The validation study demonstrated that the clinical accuracy of the Non-contact Forehead Thermometer is substantially equivalent to the predicate device.

Both the clinical and non-clinical testing detailed in this submission supports the substantial equivalence of the device.

8. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, the NTF 3000 No Touch+Forehead Thermometer. Moreover, performance tests demonstrate that any differences in their technological characteristics do not raise any new performance questions. In the other words, those engineering differences do not affect the intended use or alter the fundamental scientific technology of the device.

Thus, Non-contact Forehead Thermometer TH1009N is substantially equivalent to the predicate device.