DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2016

Biocare Asia Corporation Ltd.
Ke-Min Jen
510k Contact Person
No.260, Mayun Road, New District
Suzhou, 215129 Jiangsu
CHINA

Re: K161211
Trade/Device Name: Digital Thermometer, Model 1004/1005
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 26, 2016
Received: August 2, 2016

Dear Ke-Min Jen:

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 -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

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)*
K161211

Device Name
Digital Thermometer, Model 1004 / 1005

Indications for Use *(Describe)*
Digital Thermometer is intended to measure body temperature in axillary, oral or rectum and to be used by medical professionals in clinical and hospital environments or consumers in a home environment. It is intended for use 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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K161211

I. 510(k) Summary of Safety and Effectiveness *(Per 21 CFR 807.92)*

Trade or proprietary name	Digital Thermometer, model 1004/1005
Common Name	Digital Thermometer
Classification Name	Clinical Electronic Thermometer 21 CFR 880.2910
Class	II
Panel	80 General Hospital
Product Code	FLL
Owner/Operator	BIOCARE ASIA CORPORATION LTD. NO.260, MAYUN ROAD, NEW DISTRICT SUZHOU, JIANGSU, 215129, P.R.C. Phone: +86 (512) 6809-1772 Fax: +86 (512) 6809-7761 www.bca-medical.com
Date prepared	August 22, 2016
510k Contact Person	Dr. Jen, Ke-Min TEL: +886-3-5208829 FAX: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
Predicate Device	Kingtech Enterprises Limited KINGTECH Digital Thermometer, TT1001 K133111
Reference Device	Omron Healthcare, Inc. Clinical Electronic Thermometer, MC-246 K091676

- **Indications for Use:**

Digital Thermometer is intended to measure body temperature in axillary, oral or rectum and to be used by medical professionals in clinical and hospital environments or consumers in a home environment. It is intended for use on people of all ages.

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- **Descriptions**

The Digital Thermometers, 1004/1005, enable easy and accurate measuring over the body temperature range. It must be used in conjunction with a disposable probe cover when measuring temperature. From the construction point of view, the digital thermometer comprises of a thermistor for temperature sensing, a reference resistor for comparison of temperature, a buzzer for sounding effect, an application specified IC for calculating, and an LCD for displaying the measured temperature reading which the thermistor contacts and senses.

- **Test Principle**

The Digital Thermometers, 1004/1005, are the electronic thermometers operated by a thermistor as the temperature sensor and an application specified IC for signal processing. The basic operation principle is that a change of thermistor, caused by changes of temperature, provides a signal to application specified IC. Application specified IC gets the sensor's signal, then processes the signal and calculates the result. After that, it displays the temperature result on an LCD display.

- **Features**
  - **Patient having an elevated temperature:** indicated by red lit screen and audio beep when above 99.7 °F / 37.6 ^{0}C
  - **Measurement time:** approximately 8-10 seconds (Predictive mode) and approximately 60 seconds (Non-predictive mode)
  - **LCD read-out** with °F / °C switchable
  - **Flexible tip**
  - **Automatic shutoff** when idle for 180 sec
  - **Memory**: The last reading is automatically displayed for 2 seconds when the unit is witched ON. Up to 9 sets of memory can be stored.
  - **Storage case & battery included**

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- **Table I.1 Comparison Table**

Comparison Items	**Predicate Device (PD)**	**Subject Device**
Applicant	Kingtech Enterprises Limited,	Biocare Asia Corporation Ltd.
Proprietary (Trade) Name	Kingtech Digital Thermometer	Digital Thermometer
Model	TT1001	1004 / 1005
510(k) No.	K133111	K161211
Classification Code	FLL, Class II, 21 CFR 880.2910	FLL, Class II, 21 CFR 880.2910
Similar characteristics		
Intended uses	TT1001 Digital Thermometer is intended to measure the body temperature **orally** and to be **used by medical professionals** in clinical and hospital environments and **consumers in a home environment**. It is intended for use on **people of all ages.**	Digital Thermometer is intended to measure body temperature in **axillary, oral or rectum** and to be **used by medical professionals** in clinical and hospital environments or **consumers in a home environment.** It is intended for use on **people of all ages.**
Components	Temperature sensor, liquid crystal display, battery and circuit board	***Same components***
Sensor	Thermistor	***Same sensor type***
Signal processing and display	Using the resistance change of thermal resistor to detect body temperature and displayed through the LCD.	Same technologies: ***Same signal processing and LCD display.***
Elevated temperature indicator	Above 99.5 ^{0}F, 4 short beeps as Bi-Bi-Bi-Bi in 4 seconds	Above 99.7°F, rapid beeps and a red backlight inform the patient, ***Same audio beeps***
Display Resolution	0.1 ^{0}F	*0.1 ^{0}F* ***Same display resolution:***
Response time	60 sec	**8-10 sec** – predictive mode **60 sec** – non predictive mode ***Same response times under non-predictive mode.***
Reference standard	EN 12470-3:2000+A1:2009 ASTM E1112-00:2011 IEC 60601-1:2005 IEC 60601-1-2:2007	EN 12470-3: 2000+A1:2009 ASTM E1112-00:2011 IEC 60601-1:2005 IEC 60601-1-11:2010 IEC 60601-1-2:2007 ***One more reference standard, IEC 60601-1-11***

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Used with probe cover	YES	***YES***
Patient contacting material Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2010	***Non-sterile & single-use 510(k)-clearance probe cover with the same biocompatibilities tests***
Cleaning / disinfection info	Cleaning & disinfecting the device after each use with 75% isopropyl alcohol	***Same cleaning /disinfection process***
Operating temperature and humidity	60.8 ^{0}F to 104 ^{0}F 95% RH or less	60.8 °F to 104°F 95% RH or less ***Same operating conditions as PD***
Different characteristics		
Measurement site	Oral	Axillary, oral or rectum ***2 more sites choices than PD.***
Storage temperature and humidity	-13 ^{0}F to 131 ^{0}F 95% RH or less	-4 °F to 131 °F 95% RH or less ***Different storage conditions.***
Power requirements	1.5V, LR41	3.0 V, CR2032 ***Same button-like batteries, but with different voltages,***
Measurement range	89.6 ^{0}F to 111.2 ^{0}F	89.6 °F ~109.2 °F ***Narrower measurement range than PD***
Accuracy	±0.2 ^{0}F for the range of 98 ^{0}F to 102.2 ^{0}F	±0.1 ^{0}C at 33.0 ^{0}C, ±0.1 ^{0}C at 36.0 ^{0}C ±0.1 ^{0}C at 38.0 ^{0}C, ±0.1 ^{0}C at 40.0 ^{0}C ±0.1 ^{0}C at 42.0 ^{0}C ***They have slightly different measurement accuracies, but they all met the ASTM 1112-00:2011.***
Weight (w/ battery)	15g	30g ***They have different weights.***
Dimensions (L*W*H) mm	118 x 20 x 12 mm	134.2 x 35.1 x 15.1 mm ***They have different size dimensions.***
Auto power off	Yes, when idle for 10 min	Yes, when idle for 3 min ***Better performance of energy saving function than PD***
Patient contacting material	Non-sterile & single-use probe cover (PVC film)	***Non-sterile & single-use 510(k)-clearance probe cover (EVA film)***
Color (inks/ dyes)	Yes	Yes Pigment (YELLOW Ferro1020)

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- **Substantial Equivalence Discussion**
  - A claim of substantial equivalence is made to *Kingtech Digital Thermometer TT1001 (K133111).* The indications for use, the measurement principle and technologies are the same. There are no new concerns raised.
  - The subject device has two more sites choices than PD, i.e. under arm or rectum sites. Since the accuracy performances under arm and rectum sites are validated by the relevant bench performance testing, there are no safety or effectiveness concerns raised.
  - The storage temperature range of the subject device is different from those of PD, and the maximum storage humidity ranges of both devices are to be 95% RH or less. The storage conditions are confirmed to be effective and safe after we did the storage environment testing. If the user stores the subject device according to the prescribed storage conditions, there is no any concern raised.
  - Both of them use the same button-like batteries but with different voltages. The battery information is shown in the user manual and on the device itself, and the users can replace and install a correct type battery without question. There is no concern raised.
  - The slight differences of maximum measurement points 109.2 °F for the subject device are 2 degrees less than PD. Since these differences are so small, they will not raise any new concern.
  - The accuracies of the subject and predicate devices are different. The subject device passes the relevant accuracy testing, in which results show the accuracies as

    $\pm 0.1\ ^{0}C$ at $33.0\ ^{0}C$,
    $\pm 0.1\ ^{0}C$ at $36.0\ ^{0}C$
    $\pm 0.1\ ^{0}C$ at $38.0\ ^{0}C$,
    $\pm 0.1\ ^{0}C$ at $40.0\ ^{0}C$
    $\pm 0.1\ ^{0}C$ at $42.0\ ^{0}C$

    for different temperature ranges. PD has the same accuracy of $\pm 0.2\ ^{0}F$ for the range of $98\ ^{0}F$ to $102.2\ ^{0}F$. For the range of $98\ ^{0}F$ to $102.2\ ^{0}F$ the accuracy of the subject device is around $\pm 0.18\ ^{0}F$. So the differences of accuracies did not raise any concern.
  - Weight of the subject device is 30g, and PD is 15g. Since most of the users are healthcare professional and the different weights will not pose any adverse events for the patients. There is no new concern raised.
  - The size dimensions of the PD and subject devices are different. This is caused by the different designs of the main housing and electric board. There is no new concern raised.

- The instructions for cleaning & disinfecting the device after each use with 75% isopropyl alcohol are the same for subject and predicate devices. There is no new concern raised.
- The auto power off functions for the subject device is when idle for 180 sec and PD is 10 min idle. We can say the subject device has better performance of energy saving. There is no new concern raised.
- The color parts of subject and predicate devices are different due to the various colorants/dyes added. But subject and predicate devices are all required to be used with probe covers for patient-contacting materials. The patient-contacting materials are probe covers, not the various color parts. Especially, the probe cover used with the subject device is already 510(k) cleared (K102508). The patient-contacting materials all passed biocompatibilities testing, and the various probe covers and different color parts did not raise new safety and effectiveness concerns.

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- **Summary of non-clinical testing**

1) Electrical Safety, EMC and Biocompatibility Test

- IEC/ EN 60601-1 2012+ CORR.1 (2014) Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC/EN 60601-1-11:2010 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
- IEC/ EN 60601-1-2:2007+AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- 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

2) Performance Test

- **Accuracy & repeatability test**: The evaluation of test results showed the uncertainty and repeatability clinical bias were 0.09 and 0.058. It all met the minimum acceptable accuracies required by BS EN 12470-3:2000+A1:2009.

Table I.2.a The pooled clinical bias and its standard deviation of subject device

Sample size	The pooled clinical bias	Bias+ 1.96 SD	Bias -1.96 SD	**Uncertainty**
120	-0.01	0.17	-0.20	**0.09**

Table I.2.b The pooled clinical repeatability of subject device

The pooled clinical repeatability evaluation	Sample size	**Repeatability clinical bias**
	120	**0.058**

- **Lab accuracy test**

Table I.3 Lab accuracy test per E1112-00:2011

Water bath temperature (^{o}C)	Maximum calculated error (^{o}C)	E1112-00:2011 acceptance criteria (^{o}C)	Verdict
33.0	0.1	±0.3	Pass
36.0	0.1	±0.2	Pass
38.0	0.1	±0.1	Pass
40.0	0.1	±0.2	Pass
42.0	0.1	±0.3	Pass

- **Display temperature range test:** Verify the measuring display range of subject device to be complied with ASTM E1112-00:2011 standard, which has the requirement of covering the minimum measuring range from 35.5 to 41 ^{o}C (96.0 to 106.0 ^{o}F), The display measuring range of subject device is specified and validated to be from 32.0^{oc} to 42.9 ^{o}C, which covers the range of 35.5 - 41 ^{o}C.

- **Drop test**

Table I.4 The greatest measurement errors after drop tests.

Per ASTM E1112-00:2011	Water bath temperature (^{o}C)	Maximum calculated error (^{o}C)	Acceptance Criteria (^{o}C)	Verdict
Drop test: Drop the subject device from a height of 1 m onto the hardwood with two directions.	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.1	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

- **Operating environment test**

Table I.5. The maximum errors in the operating environmental test are within the requirements of the accuracy requirements specified in ASTM E1112-00:2011.

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Table I.5.a.

Operating environment 1	Water bath temperature (°C)	Maximum calculated error (°C)	Acceptance Criteria (°C)	Verdict
103 °F (40 °C) 15% RH	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

Table I.5.b.

Operating environment 2	Water bath temperature (°C)	Maximum calculated error (oC)	Acceptance Criteria (°C)	Verdict
103 °F (40 °C) 80% RH	33.0	0.2	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

Table I.5.c.

Operating environment 3	Water bath temperature (°C)	Maximum calculated error (°C)	Acceptance Criteria (°C)	Verdict
60.8 °F (16 °C) 40% RH	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

Table I.5.d.

Operating environment 4	Water bath temperature (°C)	Maximum calculated error (°C)	Acceptance Criteria (°C)	Verdict
60.8 °F (16 °C) 95% RH	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

- **Storage environment test**

Table I.6. The maximum errors in the storage environmental test of subject device are within the requirements of the accuracy requirements specified in ASTM E1112-00:2011.

Table I.6.a.

Storage environment 1	Water bath temperature (°C)	Maximum calculated error (°C)	Acceptance Criteria (°C)	Verdict
-13 °F (-25 °C)	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

Table I.6.b.

Storage environment 2	Water bath temperature (^{o}C)	Maximum calculated error (^{o}C)	Acceptance Criteria (^{o}C)	Verdict
130.9 ^{o}F (55 ^{o}C) 15% RH	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

Table I.6.c.

Storage environment 3	Water bath temperature (^{o}C)	Maximum calculated error (^{o}C)	Acceptance Criteria (^{o}C)	Verdict
94.9 ^{o}F (35 ^{C}C) 95% RH	33.0	0.1	±0.3	Pass
	36.0	0.1	±0.2	Pass
	38.0	0.1	±0.1	Pass
	40.0	0.1	±0.2	Pass
	42.0	0.1	±0.3	Pass

- **EN 12470-3:2000+A1: 2009** Clinical thermometers – Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device". **Table I.7.a – Table I.7.e** show the compliance of the subject devices with the EN 12470-3:2000+A1:2009.

a) Metrological requirements

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Table I.7.a.

Item no.	Test name	Acceptance criteria	Test results	Verdict
1)	Measuring range	The subject device shall cover the minimum measuring range from 35.5-42 ^{o}C (95.9 – 109.2 ^{0}F)	The test range covers 31.7 – 44.3 ^{o}C, and it meets the acceptance criteria.	Pass
2)	Digital increment	The digital increment of the indicating unit shall be 0.1 ^{o}C (0.1 ^{0}F)	The digital increment of the indicating unit is inspected to be 0.1 ^{o}C (0.1 ^{0}F), and it meets the acceptance criteria.	Pass
3)	Maximum permissible errors under reference conditions	The maximum permissible error for the measuring range 35.5 - 42.0 ^{o}C (95.9 – 107.6 ^{0}F) shall be 0.1 ^{o}C within the ambient temperature range from 18 - 28^{o}C. Outside the measuring range of 35.5 - 42.0 ^{o}C or outside the ambient temperature range, the maximum permissible error shall not be greater than twice the specified value (0.2 ^{o}C).	The results are in compliance with the requirements of Subclause 6.2.3, and it meets the acceptance criteria.	Pass
4)	Time Response	The test sample shall display the correct temperature reading within 60 seconds.	The result is in compliance with the requirements of Subclause 6.2.4, and it meets the acceptance criteria.	Pass

5)	Maximum energy dissipation	The maximum power dissipation on probe shall be 2 mW.	The result is in compliance with the requirements of Subclause 6.2.5, and it meets the acceptance criteria.	Pass
6)	Long term stability	The maximum permissible error shall comply with Subclause 6.2.3 when placing subject device into temperature chamber for a minimum of 288 hours at a temperature of (55±2) ^{o}C.	The result is in compliance with the requirements of Subclause 6.2.6, and it meets the acceptance criteria.	Pass

b) Environmental requirements

Table I.7.b

Item no.	Test name	Acceptance criteria	Test results	Verdict
1)	Ambient operating range	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.1, and it meets the acceptance criteria.	Pass
2)	Effect of storage	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.2, and it meets the acceptance criteria.	Pass
3)	Thermal Shock	The maximum permissible error shall comply with	The result is in compliance with	Pass

		Subclause 6.2.3.	the requirements of Subclause 6.3.3, and it meets the acceptance criteria.	
4)	Humidity	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.4, and it meets the acceptance criteria.	Pass
5)	Electromagnetic compatibility	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.5, and it meets the acceptance criteria.	Pass
6)	Mechanical shock	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.6, and it meets the acceptance criteria.	Pass
7)	Water resistance	The maximum permissible error shall comply with Subclause 6.2.3.	The result is in compliance with the requirements of Subclause 6.3.7, and it meets the acceptance criteria.	

c) Construction requirements

Table I.7.c.

Item no.	Test name	Acceptance criteria	Test results	Verdict
1.1	Voltage limit indication	*The subject device shall automatically provide a visual or auditory warning when its supply voltage is not within specified limits. *The device shall meet the maximum permissible error in Subclause 6.2.3 when the voltage is within the specified limits.	The result is in compliance with the requirements of Subclause 6.4.1.1, and it meets the acceptance criteria.	Pass
1.2	Indicating unit	*Numerical values on the display shall be at least 4 mm in height. *After power-on all segments shall be activated for at least 1 second.	*The numerical values on the display are measured to be more than 4 mm in height. * After power-on all segments are activated for at least 1 second. *The results meet the acceptance criteria.	Pass
1.3	Functional safety test	*The device shall have a self-testing routine. The correct operation shall be indicated by a given display.	*The result is in compliance with the acceptance criteria. *Refer to	Pass

		*The manufacturer shall provide information as to how the self-testing routine operates and what display is to be expected.	1004/1005 user manuals.	
2)	Material	The device shall be free from biological hazards.	*The result is in compliance with the acceptance criteria. *Refer to Biocompatibility information in Section J of this 510(k) submission.	Pass

d) Electrical safety

Table I.7.d.

Item no.	Test name	Acceptance criteria	Test results	Verdict
1	Electrical safety	The device shall comply with the requirements of EN 60601-1: 1990.	The result is in compliance with the requirements of Subclause 6.5 and it meets the acceptance criteria.	Pass

e) Mechanical safety

Table I.7.e.

Item no.	Test name	Acceptance criteria	Test results	Verdict
1)	Thermometer	*Thermometers shall not have sharp ends or angles that could injure the user or patient. *The temperature probe shall be smoothly rounded in order to prevent tissue damage during use.	The result is in compliance with the requirements of Subclause 6.6.1, and it meets the acceptance criteria.	Pass
2)	Resistance to breakage	The thermometer with a housing of glass shall comply with Subclause 6.1.2.7 of prEN12470-1.	*The subject devices have no glass housing. *This test is not applicable to the subject device.	NA

- **Conclusion**

The conclusions drawn from the non-clinical tests demonstrate that the subject device performs as well as the predicate device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.