510(k) Summary

1. Contact Details

1.1 Applicant information

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2. Device information

Trade name	Non-contact Infrared Thermometer
Common name	Infrared Thermometer
Model	JPD-FR400, JPD-FR402
Classification	Ⅱ
Classification name	Thermometer, Electronic, Clinical
Product code	FLL
Regulation No.	880.2910

3. Legally Marketed Predicate Device

Trade Name	Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101
510(k) Number	K112189
Product Code	FLL
Manufacturer	Digio2 International Co., LTD.

Trade Name	Non-Contact Thermometer
510(k) Number	K131243
Product Code	FLL
Manufacturer	Shenzhen Jumper Medical Equipment Co., Ltd.

4. Device Description

The infrared thermometers (JPD-FR400, JPD-FR402) are handheld instruments which can measure human body's temperature either via the eardrum or the forehead for clinical or home use. The results can be displayed on LCD. And, the results measured by JPD-FR400 can be transmitted to mobile device (i.e. iPhone) with Bluetooth and the application "Angel Doctor" installed on a mobile device using the iOS system or the Android system. The thermometers, which are powered by AAA 1.5Vx2 Alkaline batteries, can be used for all age groups except for babies under three months.

A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the eardrum or the surface of the skin of the forehead, which is converted into temperature measurement with the unit of ℃ or ℉.

5. Intended Use/Indication for Use

The Infrared thermometers (JPD-FR400 and JPD-FR402) take human body temperature via the eardrum or forehead. They apply to all age groups except for babies under three months. Both devices apply to both professional use and home use.

6. Substantial Equivalence Comparison

Item	Proposed Device: Infrared Thermometer JPD-FR400/402	Predicate Device 1: Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101	Predicate Device 2: Non-Contact Thermometer JPD-FR100	Comments
510(k) Number	Pending	K112189	K131243	/
Product Code	FLL	FLL	FLL	Same
Intended Use &Indications for use	The Infrared thermometers (JPD-FR400, JPD-FR402) take human body temperature via the eardrum or forehead. They apply to all age groups except for babies under three months. Both devices apply to both professional use and home use.	The Thermo Pal Infrared Ear Thermometer (Model no.: ETH-l0l) is infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	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.	Different **Note 01**
Regulation Number:	21CFR 880.2910	21CFR 880.2910	21CFR 880.2910	Same
Measurement mode	Ear and Forehead measurement mode	Ear measurement mode	Forehead measurement mode	For ear measurement mode, same as Predicate device 1; For forehead measurement mode, same as Predicate device 2;

Item	Proposed Device: Infrared Thermometer JPD-FR400/402	Predicate Device 1: Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101	Predicate Device 2: Non-Contact Thermometer JPD-FR100	Comments
Measurement range	**Forehead temperature mode:** 0.0℃~100.0℃ /32.0°F~212.0 °F **Ear temperature mode:** 0.0℃~100.0℃ /32.0°F~212.0 °F	Ear canal mode: 32~43℃ （89.6~109.5℉）	Forehead temperature mode: 32.2℃~43.3℃ （90.0℉~109.9℉）	Different **Note 02**
Auto power-off while no operation	Yes	Yes	Yes	Same
℃/℉ can be switchable	Yes	Yes	Yes	Same
Working Ambient Temperature Environment	**Operating environment:** Temperature: 10°C~40°C (50°F–104°F) Humidity: 15%–95%RH, non-condensing Atmospheric pressure: 86kPa–106 kPa **Storage condition:** Ambient Temperature: -20°C to 55°C （-4°F–131°F） Relative Humidity: 0-95% RH, non-condensing Atmospheric pressure: 50kPa	1. Operating: 10℃～40℃ 2. Storage: -20℃～50℃	1. Operation: 10℃～40℃, 80% RH, non-condensing 2. Storage and transportation: Temperature:-10°C to 60°C Humidity: 0 - 95% RH, non-condensing	Similar

Item	Proposed Device: Infrared Thermometer JPD-FR400/402	Predicate Device 1: Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101	Predicate Device 2: Non-Contact Thermometer JPD-FR100	Comments
	to 106kPa			
Accuracy	1) ±0.2°C (±0.4°F) 36.0°C-39.0°C/96.8°F-102.2°F 2) ±0.3°C (±0.5°F) from 32.0°C-35.9°C/89.6°F-96.7°F 3) ±0.3°C (±0.5°F) 39.1°C-42.2°C/102.3°F-108.0°F	±0.2℃, 36～39℃ ±0.3℃, the rest (±0.4℉, 96.8～102.2℉ ±0.5℉, the rest)	Forehead temperature mode: ±0.2 ℃ (±0.4℉)	For the forehead temperature mode: same as Predicate Device 2. For the ear canal temperature mode: same as Predicate Device 1.
Display Resolution	0.1℃/0.1℉	0.1℃/0.1℉	0.1℃/0.1℉	Same
Measurement distance	1-5cm	/	1-6cm	Similar with Predicate Device 2.
Power supply	2×1.5Vdc AAA Alkaline batteries	Two 1.5Vdc Alkaline Managnese batteries (AAA)	2×1.5Vdc AAA Alkaline batteries	Same
Low power indication	Yes	Yes	Yes	Same
Display screen	LCD	LCD	LCD	Same
Memory	20 sets	Unknown	20 sets	Same as Predicate Device 2.
Bluetooth function	JPD-FR400, yes JPD-FR402, no.	No	No	For JPD-FR400, different **Note 03**

Item		Proposed Device: Infrared Thermometer JPD-FR400/402	Predicate Device 1: Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101	Predicate Device 2: Non-Contact Thermometer JPD-FR100	Comments
Waterproof		IP22	No	No	Different **Note 04**
Conformance standard /guidance	Electric safety and EMC	AAMI ANSI ES60601-1:2005/(R)2012+ A1:2012 IEC 60601-1-2: 2014 IEC 60601-1-11:2015	IEC 60601-1 IEC 60601-2 IEC 60601-1-11	IEC 60601-1:1988+A1:1991+ A2:1995 IEC 60601-1-2:2007 IEC 60601-1-11:2010	SE
	Risk management	ISO 14971:2007	ISO 14971	ISO 14971:2007	SE
	Biocompatibility	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:20	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	SE
	Performance	ASTM E 1965-98 (Reapproved 2009) ISO 80601-2-56: 2009	ASTM E1965: 2003	ASTM E 1965-98(2009)	SE

Discussion:

Note 01:
For the ear canal measurement mode, the subject devices' intended population is smaller than that of Predicate device 1.
For the forehead measurement mode, the subject devices' intended population is smaller than that of Predicate device 2.

Note 02:
The subject devices' measuring range is larger than that of both predicate device 1 and predicate device 2. Due to the subject devices also apply to measuring the environmental temperature, so their measuring range is larger.

Note 03:
JPD-FR400 has passed FCC, EN301489-1, EN301489-17, EN 300328 and wireless coexistence test.

Note 04:
The subject device has passed the IEC60601-1 and the IEC60601-1-11 test.

7. Non-clinical Performance Testing

The performance data in compliance with the following standard were provided in support of the substantial equivalence determination.

AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012: 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;

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 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;

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;

ASTM E 1965-98 (Reapproved 2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature;

EN 300 328 : 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;
ETSI EN 301 489-1: Electromagnetic compatibilityand Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1: Common technical requirements;

ETSI EN 301 489-17: Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems;

8. Clinical performance

The clinical performance test is conducted according to ASTM E 1965-98 (Reapproved 2009). The test report showed the clinical performance of proposed devices complied with the requirements of ASTM E 1965-98 (Reapproved 2009).

9. Conclusions

The infrared thermometer JPD-FR400 and JPD-FR402 have the similar intended use with the predicated device 1 on ear canal mode and have the similar intended use with the predicate device 2 on forehead mode, the non-clinical performance tests and the clinical tests demonstrated adequate performance. The Infrared Thermometer JPD-FR400 and JPD-FR402 are substantially equivalent to the predicate devices, K112189 and K131243.