510(K) SUMMARY

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.87(h) and 21 CFR 807.92.

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Name of the Devices:

- **Device Common Name**: Infrared Thermometer
- **Device Proprietary Name**: AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606)
- **Classification Name**：Thermometer, electronic, clinical
- **Regulation Number:**21CFR 880.2910
- **Product Code**：FLL
- **Review Panel:** General Hospital

Legally Marketed Predicate Device(s):

K131243 Non-contact Infrared Thermometer, Model JPD-FR 100

Indications for Use:

The AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606) is

intended for body temperature measurement from the auditory canal for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

Device Description:

The AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606) is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal.

It 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 thermometer consists mainly of two parts - an IR sensor with a built-in ambient temperature sensor and the associated circuit. To measure body temperature, the probe of the thermometer is inserted into a patient's outer ear canal. Pressing the activation button to start the measurement of target's infrared radiation. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The final measured temperature will be appeared on a LCD display. The total operation takes a few seconds.

Comparison to Predicate Devices:

The Substantial Equivalence Comparison Chat is provided as follows:

Table1: Substantial Equivalence Comparison Chat between AT-601 and JPD-FR 100

Comparison items	AT-601 infrared thermometer	JPD-FR100 infrared dual-mode thermometer	Comparison results
Name	Infrared thermometer	Infrared dual-mode thermometer	Similar
Model	AT-601	JPD-FR100	
Manufacturer	SHENZHEN ACURIO INSTRUMENTS CO., LTD.	Shenzhen Jumper Medical Equipment Co., Ltd.	
Management category	IIa	IIa	Identical
510(K) Number	/	K131243	N/A
CE Number	/		
Structure	Mini body part, probe, lens filter, LCD screen, battery door	Body part, probe, lens filter, LCD screen, battery door	Similar

Comparison items		AT-601 infrared thermometer	JPD-FR100 infrared dual-mode thermometer	Comparison results
Materials		ABS plastic is used on the shell, and stainless steel material is used on the temperature sensor.	ABS plastic is used on the shell, and stainless steel material is used on the temperature sensor.	Similar
Basic operating principle		The product provides noninvasive and rapid body temperature measurement by detecting the infrared energy emitted from the tympanic membrane, and shows the results by the LCD.	The product provides noninvasive and rapid body temperature measurement by detecting the infrared energy emitted from the tympanic membrane, or forehead and shows the results by the LCD.	Same
Primary technical performance indexes	Battery	D.C.3.0V, CR2032	D.C. 3.0V, two 1.5V AAA batteries	Similar
	Display unit	0.1 ℃	0.1 ℃	Identical
	Measuring range	34°C~42.2°C	Forehead mode: 32°C~42.2°C Ear mode: 0°C~100°C	
	Accuracy	± 0.2°C (35°C~42°C), ± 0.3°C (outside the range of 35°C~42°C)	Ear mode: ± 0.2°C Forehead mode: ± 0.3°C	Similar
	Memory function	9 sets of storage data	20 sets of storage data	
	Dimensions (LWH)	58mm×58mm×66mm	N/A	N/A
	Weight	Approx. 80g (including batteries）	N/A	N/A
Intended use		It is intended for the intermittent measurement and monitoring of body temperature.	It is intended for the intermittent measurement and monitoring of body temperature.	Same
Measuring site		Ear	Ear, forehead	Same when measuring ear temperature

Table1: Substantial Equivalence Comparison Chat between AT-606 and JPD-FR 100

Comparison items	AT-606 infrared thermometer	JPD-FR100 infrared dual-mode thermometer	Comparison results
Name	Infrared thermometer	Infrared dual-mode thermometer	Same
Model	AT-606	JPD-FR401	
Manufacturer	SHENZHEN ACURIO INSTRUMENTS CO., LTD.	Shenzhen Jumper Medical Equipment Co., Ltd.	
Management category	IIa	IIa	Identical
510(K) Number	/	K131243	N/A

Comparison items		AT-606 infrared thermometer	JPD-FR100 infrared dual-mode thermometer	Comparison results
CE Number		/		
Structure		Body part, probe, lens filter, LCD screen, battery door	Body part, probe, lens filter, LCD screen, battery door	Similar
Materials		ABS plastic is used on the shell, and stainless steel material is used on the temperature sensor.	ABS plastic is used on the shell, and stainless steel material is used on the temperature sensor.	Similar
Basic operating principle		The product provides noninvasive and rapid body temperature measurement by detecting the infrared energy emitted from the tympanic membrane, and shows the results by the LCD.	The product provides noninvasive and rapid body temperature measurement by detecting the infrared energy emitted from the tympanic membrane or forehead, and shows the results by the LCD.	Same
Primary technical performance indexes	Battery	D.C.3.0V, 2*AAA	D.C. 3.0V, two 1.5V AAA batteries	Similar
	Display unit	0.1 °C	0.1 °C	Identical
	Measuring range	34°C~42.2°C	Forehead mode: 32°C~42.2°C Ear mode: 0°C~100°C	
	Accuracy	± 0.2°C (35°C~42°C), ± 0.3°C (outside the range of 35°C~42°C)	Ear mode: ± 0.2°C Forehead mode: ± 0.3°C	Similar
	Memory function	9 sets of storage data	20 sets of storage data	
	Dimensions (LWH)	137mmX40mmX56mm	N/A	N/A
	Weight	Approx. 80g (including batteries）	N/A	N/A
Intended use		It is intended for the intermittent measurement and monitoring of body temperature.	It is intended for the intermittent measurement and monitoring of body temperature.	Identical
Measuring site		Ear	Ear, forehead	Similar when measuring ear temperature

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

The Sponsor performed a risk assessment based on the differences from the predicate device and determined that the following non-clinical testing was necessary to demonstrate that the changes did not introduce any new risks to the subject device.

Laboratory testing was conducted to validate and verify that the thermometers continued to meet all requirements of related international standards, including electrical safety, EMC, software, biocompatibility. Results of these tests demonstrated compliance to the requirements of the below consensus standards and FDA Guidance documents.

Electrical Safety and Performance: *1. IEC 60601-1:2005+A1:2012;* *2. ISO 80601-2-56:2009.*
Medical Electrical Equipment and medical Electrical Systems Used in the Home Healthcare Environment: *1. IEC 60601-1-11:2010+CORR.1:2011.*
Electromagnetic Compatibility: *1. IEC 60601-1-2:2007.*
Biocompatibility: *1. ISO 10993-5:2009* 2. *ISO 10993-10:2010*
Software: *1. General Principles of Software Validation – Final Guidance for Industry and FDA Staff.*
Clinical Electronic Thermometers Guidance: *1. Guidance on the content of Premarket Notification[510(k)] Submission for clinical electronic thermometers*

Therefore, we conclude that the AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606) is substantially equivalent to the predicate device.

Discussion of Clinical Tests Performed:

In order to demonstrate that the subject device did not introduce any new risks in comparison to the subject device a clinical accuracy evaluation has been conducted according to clause 201.102 of ISO 80601-2-56:2009. Clinical test results demonstrated that the subject device performs substantially equivalent to the predicate device.

Conclusions:

The AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606) has the same intended use and similar characteristics as the predicate device. And based on performance data, we conclude that the AT-6XX Series Infrared Thermometer (with models AT-601 and AT-606) is substantially equivalent to the predicate device.