December 20, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Jack Wang
Deputy Chief
Room 301&4F, Blk A, Building A, Jingfa IM Park, Xiaweiyuan,
Gushu Community, Xixiang, Baoan
Shenzhen, Guangdong 518126
China

Re: K221039
Trade/Device Name: Infrared Thermometer, models AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T, AOJ-20R and AOJ-20Y
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 17, 2022
Received: November 28, 2022

Dear Jack Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

Joyce M. Whang, Ph.D.
Deputy Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221039

Device Name
Infrared Thermometer, models AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T, AOJ-20R and AOJ-20Y

Indications for Use *(Describe)*

The Infrared thermometer is intended to measure human body temperature of people over three months old from the eardrum or forehead. It is indicated to be used in homecare and healthcare environments.

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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510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Shenzhen AOJ Medical Technology Co., Ltd. Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China TEL: 86 755-27786026
Contact Person:	Jack Wang
Prepare date:	December 20, 2022
2. Device name and classification:	**Device Name:** Infrared Thermometer **Models:** AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T, AOJ-20R and AOJ-20Y **Classification Name:** 21 CFR 880.2910 Clinical Electronic Thermometers **Product code:** FLL **Regulatory Class:** Class II
3. Predicate Device:	Shenzhen AOJ Medical Technology Co., Ltd. AOJ-20A cleared under K182133. The predicate has not been subject to any recall.
4. Device Description:	The AOJ-20 series Infrared thermometer is a handheld device, 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. The device operates in adjusted mode, and the reference body site of output temperature is oral. The measurement distance for forehead mode is 0 cm ~ 3 cm. The thermometers are powered by AAA 1.5V×2 alkaline batteries. A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the eardrum or the surface of the skin of forehead, which is converted to the equivalent oral temperature with the unit of ℃ or ℉. All the models share the similar design and the same critical components. The major differences include: - Mechanical changes and the corresponding hardware adjustment happened to AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T, AOJ-20R and AOJ-20Y - In the measurement function, two measurement modes are distinguished between children and adults for AOJ-20B and AOJ-20E.
6. Indications for Use:	The Infrared thermometer is intended to measure human body temperature of people over three months old from the eardrum or forehead. It is indicated to be used in homecare and healthcare environments.

7. Predicate Device Comparison

Table 1 Comparison between the predicate AOJ-20A and the subject devices

ITEM	Proposed Device AOJ-20 series/K221039	Predicate Device AOJ-20A/K182133	Comparison Result
Manufacture	Shenzhen AOJ Medical Technology Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	Same
Indications for Use	The Infrared thermometer is intended to measure human body temperature of people over three months old from the eardrum or forehead. It is indicated to be used in homecare and healthcare environments.	The Infrared thermometers (AOJ-20Aand AOJ-20B) 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.	Different [1]
Operational Specifications			
Operational Principle	Infrared radiation detection	Infrared radiation detection	Same
Measuring Mode	Forehead and ear	Forehead and ear	Same
Measurement Range	32.0°C～42.9°C （89.6°F~109.2°F)	32.0°C～42.9°C （89.6°F~109.2°F)	Same
Measurement Distance	0 cm for ear mode 0~3 cm for forehead mode	0 cm for ear mode 0~3 cm for forehead mode	Same
Accuracy	±0.2°C(0.4°F)	±0.2°C(0.4°F)	Same
Memory Data Limit	The last 40 values (except AOJ-20A is 10 values)	The last 20 values	Different [2]
Product configuration	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	Same
Operation Mode	Adjusted Mode	Adjusted Mode	Same
Age toggle switch	Used for sub-mode switch for children forehead measurement, available for AOJ-20B and AOJ-20E only	Not available	Different [3]
Sub-mode selection	Button for sub-mode selection of children forehead measurement, available for AOJ-20M only	Not available	Different [3]
Toggle Switch for unit switch	Available for all models except AOJ-20Y, switch the unit by toggle switch	Not available, unit switch is realized by button operation	Different [4]
Touch function	Realize the mode switch by touching, available for AOJ-20Y only	Not available	Different [5]
Temperature unit and conversion	Dual temperature units “°C” and “°F” optional, and the two units can convert by the conversion	Dual temperature units “°C” and “°F” optional, and the two units can convert by the conversion	Same
Display	0.1°C/°F, LCD(except AOJ-20Y is LED)	0.1°C/°F, LCD	Same

Operating Environment	Temperature: 5°C~ 40°C (50°F–104°F) Humidity: 15%–95% RH, non-condensing Atmospheric pressure: 70–106 kPa	Temperature: 10°C~ 40°C (50°F–104°F) Humidity: 15%–95% RH, non-condensing Atmospheric pressure: 70–106 kPa	Different [6]
Storage Environment	Ambient Temperature: -20°C to 55°C (-4°F–131°F） Relative Humidity: <95% RH, non-condensing Atmospheric pressure: 50kPa to 106kPa	Ambient Temperature: -20°C to 55°C (-4°F–131°F） Relative Humidity: <95% RH, non-condensing Atmospheric pressure: 50kPa to 106kPa	Same
Power supply	2 X 1.5V AAA Alkaline battery	2 X 1.5V AAA Alkaline battery	Same
Physical Specifications			
Weight	AOJ-20A: 60g (without battery) AOJ-20B: 75g (without battery) AOJ-20C: 60g (without battery) AOJ-20D: 73g (without battery) AOJ-20E: 80g (without battery) AOJ-20F: 73g (without battery) AOJ-20H: 73g (without battery) AOJ-20M: 76g (without battery) AOJ-20T: 98g (with battery) AOJ-20R: 80g (with battery) AOJ-20Y: 93g (with battery)	90g (battery included)	Different [7]
Dimensions (mm×mm×mm)	AOJ-20A: 143×35×41 AOJ-20B: 163.5×40×41 AOJ-20C: 143×35×41 AOJ-20D: 163.5×40×41 AOJ-20E: 143×35×41 AOJ-20F: 163.5×40×41 AOJ-20H: 163.5×40×41 AOJ-20M: 162×43×35 AOJ-20T: 162×43×35 AOJ-20R: 143×35×41 AOJ-20Y: 166×38×40	146mm *52 mm *40 mm	
Biological Specifications			
Patient Contacting Materials	PC+ABS	PC+ABS	Same
Patient Contacting	Skin surface contacting, Less than 24 h	Skin surface contacting, Less than 24 h	Same
Biocompatibility Standard	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	Same
Biocompatibility Testing Items	In vitro Cytotoxicity Skin Sensitization Irritation	In vitro Cytotoxicity Skin Sensitization Irritation	Same

Justification for the differences:

1) Different Indications for Use

As indicated in the comparison table, the application scenario of the subject device and the predicate device can be used both in hospital and home, they have same intended use, they are just some language description differences. The difference does not raise new safety and effectiveness issues.

2) Different memory capacity

The predicate device can store up to 20 values, while the subject device has the capacity to store 40 memories(except AOJ-20A is 10 values), this memory function has been verified during the design and development process. The test results met the requirements.

The difference does not raise new safety and effectiveness issues.

3) Different sub-mode design

AOJ-20B and AOJ-20E can switch between 3M to 6Y, 6Y to 12Y and greater than 12Y by Age toggle, and AOJ-20M can also realize the sub-mode selection of children forehead measurement by button operation, while the predicate device does not have the sub-mode selection. This function has been well verified and validated before product release. The difference does not raise any new safety and effective issues.

4) Different Unit Switch Method

The unit toggle switch function is available for all models except AOJ-20Y, but this is not available for the predicate device. This function has been well verified and validated before product release. The difference does not raise any new safety and effective issues.

5) Different Touch Function

The AOJ-20Y is designed to be performed by touch operation, which is different from the button operation of the predicate device, and all the functions of this model have been well demonstrated to be safety and effectiveness after the verification and validation data. The difference does not raise any new safety and effective issues.

6) Different Operation Environments

Minor difference to operation environments between the subject device and the predicate device, but the system has been proved to be safe and effective since the performance testing was conducted under the suggested environment per ISO 80601-2-56: 2017and the results met the requirements. The difference does not raise new safety and effectiveness issues.

7) Different Physical Specifications

The weight and size of the subject device and predicate are different. The performance testing was conducted in accordance with standards. The test results met requirements. The differences do not raise new safety and effectiveness issues.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Data:

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

Biocompatibility testing

The biocompatibility evaluation for the thermometer were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered surface-contacting, limited exposure (-less than 24 hours). And the evaluation of testing is summarized as below.

Test name	Test standard	Evaluation endpoint	Summary results
In vitro Cytotoxicity	ISO 10993-5	No potential cytotoxicity is allowed	No potential cytotoxicity
Skin Sensitization	ISO 10993-10	No sensitization should be observed	No sensitization observed (test sample score 0)
Skin Irritation	ISO 10993-10	No irritation should be observed	Negligible (no observed primary irritation, test sample score 0).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the thermometer device. The device complies with the IEC 60601-1 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, IEC 60601-1-11 *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*, and the IEC 60601-1-2 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests* standard for EMC.

Bench Testing

Bench testing was conducted on the thermometer device, consisting of all the accessories in the system. The system complies with the ISO 80601-2-56 *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement* for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and the test results demonstrated the software function met the requirements. The 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.

Clinical data:

The clinical testing was conducted per Section 201.102 of ISO 80601-2-56 on all the models. Clinical accuracy validation was carried out on people over three month indicated in the instructions for use. The number of subjects in each age group met the minimum number requirements. The specific number of tested subjects, age groups and test results are described as below.

Item / Model	Age group		Subject number in total for ear mode	Subject number in total for forehead mode
	Ear mode	Forehead mode		
AOJ-20A	A2, B, C	A2, B, C0, C3	138	138
AOJ-20B	A2, B, C	A2, B, C1, C2, C3	136	136
AOJ-20C	A2, B, C	A2, B, C0, C3	137	137
AOJ-20D	A2, B, C	A2, B, C0, C3	138	138
AOJ-20E	A2, B, C	A2, B, C1, C2, C3	137	137
AOJ-20F	A2, B, C	A2, B, C0, C3	137	137
AOJ-20H	A2, B, C	A2, B, C0, C3	135	135
AOJ-20M	A2, B, C	A2, B, C1, C2, C3	137	137
AOJ-20T	A2, B, C	A2, B, C0, C3	137	137
AOJ-20R	A2, B, C	A2, B, C0, C3	137	137
AOJ-20Y	A2, B, C	A2, B, C0, C3	137	137

Age group is defined as below:

- A1 1 month up to 3 months
- A2 3 months up to one year

- B older than one and younger than five years
- C older than five years
- C1 older than five and younger than six years
- C2 older than six and younger than 12 years
- C3 older than 12 years

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. Based on the performance testing, comparison and analysis above, the subject AOJ-20 series Infrared Thermometer is substantially equivalent to the predicate device.