May 25, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Queena Chen
Regulatory Director
Room 301&4F, Blk A, Building A, Jingfa IM Park
Xiaweiyuan, Gushu Community, Xixiang, Baoan District
Shenzhen, Guangdong 518126
China

Re: K213485
Trade/Device Name: Digital Thermometer, Models: AOJ-25A, AOJ-25B, AOJ-25C, AOJ-25D and AOJ-25E
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 20, 2022
Received: April 25, 2022

Dear Queena Chen:

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,

David Wolloscheck
For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K213485

Device Name
Digital Thermometer, Models: AOJ-25A, AOJ-25B, AOJ-25C, AOJ-25D and AOJ-25E

Indications for Use *(Describe)*
The AOJ-25 series Digital Thermometer (except AOJ-25B) are designed as reusable battery-operated electronic device, and intended for the measurement of oral, armpit and rectal temperature for people of all ages at home.

The AOJ-25B is intended to measure temperature rectally only for people of all ages at home as well. The device is reusable.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K213845 - 510(k) Summary

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

| | |
|---|---|
| **1. Submitter:** | Shenzhen AOJ Medical Technology Co., Ltd.<br>Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China<br>TEL: 86 755-27786026 |
| **Contact Person:** | Jack Wang |
| **Prepare date:** | May 24, 2022 |
| **2. Device name and classification:** | **Trade Name:** Digital Thermometer<br>**Models:** AOJ-25A, AOJ-25B, AOJ-25C, AOJ-25D and AOJ-25E<br>**Common Name:** Clinical Electronic Thermometer<br>**Classification Number/Name:**<br>21 CFR 880.2910<br>Clinical Electronic Thermometers<br>**Product code:** FLL<br>**Regulatory Class:** Class II |
| **3. Reason for Submission:** | New Application. No prior submission for this device before. |
| **3. Class III device statement** | Not applicable, the subject device is a Class II device. |
| **4. Predicate Device(s):** | Joytech Healthcare Co., Ltd, Digital Thermometer, Model DMT-4726, K183393 |
| **5. Device Description:** | The digital thermometer is designed as hand-held device which can measure human body's temperature orally, axillary (under the arm), or rectally. The results can be displayed on LCD.<br>The digital thermometers have several functions, such as beep indication, °C and °F unit switchable, low battery detection, memories, three-color backlight, auto automatic power off functions.<br>The device is a predictive digital thermometer. Users only need 10 seconds for quick reading, and will display the temperature value on the screen. |
| **6. Indications for Use:** | The AOJ-25 series Digital Thermometer (except AOJ-25B) are designed as reusable battery-operated electronic device, and intended for the measurement of oral, armpit and rectal temperature for people of all ages at home.<br>The AOJ-25B is intended to measure temperature rectally only for people of all ages at home as well. The device is reusable. |

**7. Substantial Equivalence Discussion**

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Table 1 Comparison between predicate DMT-4726 and the subject device AOJ-25 series

| ITEM | Proposed Device<br>AOJ-25A, AOJ-25B, AOJ-25C, AOJ-25D, AOJ-25E | Predicate Device<br>DMT-4726/K183393 | Comparison Result |
|---|---|---|---|
| Manufacturer | Shenzhen AOJ Medical Technology Co., Ltd. | Joytech Healthcare Co., Ltd | |
| Intended Use/Indications for Use | The AOJ-25 series Digital Thermometer(except AOJ-25B) are designed as reusable battery-operated electronic device, and intended for the measurement of oral, armpit and rectal temperature for people of all ages at home. The AOJ-25B is intended to measure temperature rectally only for people of all ages at home as well. The device is reusable | The Digital Thermometers DMT series(Except DMT-455) are intended to measure the human body temperature in regular mode orally, rectally or under the arm. And the devices are reusable for clinical or home use on people of all ages, including children under 8 with adult supervision. | Different [1] |
| **Operational Specifications** | | | |
| Operational principle | A change of thennistor resistance, caused by changes of temperature. The resistance is measured by MCU, so changes of temperature will correspond to changes of resistance | A change of thermistor resistance, caused by changes of temperature. The resistance is measured by MCU, so changes of temperature will correspond to changes of resistance | Same |
| Sensor | Thermistor | Thermistor | Same |
| Components | Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module. | Sensor, buzz film, housing, stainless steel cap, LCD display , measurement control module. | Same |
| Signal processing and display | Internal firmware and local LCD display | Internal firmware and local LCD display | Same |
| Predictive mode | YES | Optional | Different [2] |
| Measurement site | orally, rectally or under the arm (except AOJ-25B, rectal only) | orally, rectally or under the arm | Same |
| Measurement range | 32.0°C- 42.9°C | 32.0°C- 43.9°C | Different [2] |
| Accuracy | 0.1°C (35.5°C-42°C)<br>0.2°C(< 35.5°C or > 42.0°C) | ±0.1°C (35.5°C- 42.0°C)<br>±0.2°C(< 35.5°C or > 42.0°C) | |
| Memory data | 10 memories | 10 memories | Same |
| Automatic shutdown | YES | YES | Same |
| Temperature unit and conversion | Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically | Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically | Same |
| Operating environment | Temperature: 10°C- 40°C<br>Humidity: 30%- 85% RH, non-condensing<br>Atmospheric pressure: 70- 106 kPa | Temperature: 5°C- 40°C<br>Humidity: 15%- 95% RH, non-condensing<br>Atmospheric pressure: 70- 106 kPa | Different [3] |
| Storage environment | Ambient Temperature:<br>- 20°c to 55°C<br>Relative Humidity: 10-93% RH, non-condensing<br>Atmospheric pressure: 70kPa to 106kPa | Ambient Temperature:<br>- 20°c to 55°C<br>Relative Humidity: 0-95% RH, non-condensing<br>Atmospheric pressure: 50kPa to 106kPa | |
| Battery type | One 3.0V CR2032 battery | One 3.0V CR2032 battery | Same |
| Applied Standards | | | |
| Electrical safety | IEC 60601-1<br>IEC 60601-1-11 | IEC 60601-1<br>IEC 60601-1-11 | Same |

| | | | |
|---|---|---|---|
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | Same |
| Biocompatibility | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10 | Same |
| **Physical Specifications** | | | |
| Weight | AOJ-25A/AOJ-25C/AOJ-25E:<br>Approx. 23 grams without battery<br>AOJ-25B: Approx. 26 grams including battery | Approx. 40 grams including battery | Different [4] |
| Dimensions<br>(Lx Wx H) | AOJ-25A/AOJ-25C/AOJ-25E:<br>142mmx30mmx 14mm<br>AOJ-25B: 93mm x 34.5mm x 18mm | 106 mm x 32 mm x 25 mm | |
| Display screen | LCD | LCD | Same |
| **Biological Specifications** | | | |
| Patient Contacting Materials | ABS,TPU,Stainless steel | ABS,TPE,Stainless steel | Different [5] |
| Patient Contacting | Surface-contacting,<br>Less than 24 h | Surface-contacting,<br>Less than 24 h | Same |
| Biocompatibility evaluation | Cytotoxicity, skin sensitization and irritation | Cytotoxicity, skin sensitization and irritation | Same |

**Justification for the differences:**

1) Different Indications for Use
   As indicated in the comparison table, the application scenario of the predicate device can be used both in hospital and home, while the subject device can be used at home. The absence of application in clinical use reduces the operation risks, no raise of new questions on the safety and effectiveness.
2) Different measurement range
   The subject device measurement range has been evaluated per the internal standards ISO 80601-2-56, the results tell the accuracy can be matched as claimed, no extra risk will be introduced due to the minor difference.
3) Different Operation, storage, and transportation Environments
   Minor difference to operation and storage and transportation environments for the subject device, but the system has been proved to be safe and effective since the safety testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as declared under the suggested conditions. So those changes will not cause any safety and effectiveness problem.
4) Different Physical Specifications
   The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor different ill not raise any safety and effectiveness questions.
5) Different Patient Contacting Materials
   Minor different material used for the housing, but both comply with the same standards, and evaluated to be safe after the biocompatibility testing as defined in Annex I of ISO 10993-1. Therefore, this material difference will not cause any safety and effectiveness problem.

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The differences between the subject and predicate devices do not raise different

questions of safety or effectiveness. Moreover, as demonstrated in the bench testing, the different technological characteristics do not affect the safety and effectiveness of the subject device.

## 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 digital 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 contact classification is considered mucosal membrane contacting for a duration of less than 24 hours. The battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the digital 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 digital 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 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 ACCURACY in each adjusted mode was validated per the requirements defined in clause 201.102 of international standard ISO 80601-2-56. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consists of a minimum of 90 subjects as required, and divided into four age groups as defined in Table 201.102 of the standard shown as below.

**Table 201.102 — Subject age groups**

| Age group | Age[11] |
|---|---|
| A1 | 0 up to 3 months |
| A2 | 3 months up to 1 year |
| B | older than 1 year and younger than 5 years |
| C | older than 5 years |

No single measurement error exceeding the allowable limit, provides a 99% confidence. A reference device is introduced as required by the standard, and the acceptance criteria is that clinical accuracy of the subject device is at least the same as that of the reference, and the accuracy is ±0.1°C as claimed in the manual.

## Summary

Based on the non-clinical performance data as documented in the device development, the subject devices were found to have a similar safety and effectiveness profile as the predicate device.

## 9. Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety and effectiveness. Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the AOJ-25 series Digital Thermometer is substantially equivalent to the predicate device.