March 14, 2025

AION Biosystems Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K250401
Trade/Device Name: AION TempShield™
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 12, 2025
Received: February 12, 2025

Dear Dave Yungvirt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250401

Device Name
AION TempShield™

Indications for Use *(Describe)*
The AION TempShield™ is a battery powered wearable thermometer intended for continuous measurement of human body temperature on the upper chest via wireless communication to a smart device application. AION TempShield™ is intended for single-use and for persons aged 1 year and older in either healthcare facilities or home 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K250401 510(k) Summary

Traditional 510(k)

AION TEMPSHIELD™

1. SUBMITTER/510(K) HOLDER

AION Biosystems Inc.
175 Cabot street, suite 100,
Lowell, MA 01854

Contact Name: Carl Shubitowski (Director of Quality & Regulatory)

Email: Carl.Shubitowski@aionbiosystems.com Telephone: (617) 279-3881

Date Prepared: February 1, 2025

Reason for 510(k): New device

2. DEVICE NAME

Proprietary / Trade Name:	AION TEMPSHIELD™
Common/Usual Name:	Clinical Electronic Thermometer
Classification Name:	Clinical Electronic Thermometer
Classification Regulation:	21 CFR 880.2910
Product code:	FLL
Classification:	Class 2
Medical Specialty (Panel):	General Hospital

3. PREDICATE DEVICES

Predicate Type	Device Name	Manufacturer	510(k)	Product Code and Regulation
Primary	iTempShield	AION Biosystems	K232010	FLL, 21 CFDR 880.2910
Reference / Secondary	Fever Scout	VivaLNK	K181013	FLL, 21 CFDR 880.2910

4. DEVICE DESCRIPTION

The AION TempShield™ is a wearable device that senses body temperature and communicates with an app on a smartphone or tablet or certified gateway device . When the AION TempShield™ is connected to the device, it sends all temperature measurements automatically.

The AION TempShield™ can be worn for up to 90 days to check current temperature and to allow viewing of historical temperature measurements. The device has the ability to share the data with the clinician if the clinician has established an AION account.

The temperature measurements are in degrees Fahrenheit (°F), but can also be configured to display in degrees Celsius (°C).

Circuit board with Bluetooth and NFC (near field communication chip). A phone with NFC is used to turn on the device. The device communicates with a phone that has the AION TempShield app installed. The circuit card has two digital temperature sensors and a 32 MHz clock. The device is designed to have a minimum operating range of 10 meters and provides a 2 dBm signal to the radio. The AION TempShield™ is shipped in a shelf mode power condition (4uA) and can be on the shelf for 24 months before the battery is depleted below the 90-day threshold.

The Bluetooth transmissions are encrypted using the on-board encryption. Each device has a random pairing code that must be typed in before the sensor and the mobile device can communicate. The modulation for the low energy Bluetooth is QFSK and the device has been certified and registered with the FCC for a class II device (at home use). The hospital use is covered under this classification.

The smart phone application requires that the user allow for notifications, has access to location services, and enables both NFC and Bluetooth services to fully activate the AION TempShield™. Each AION TempShield™ has a unique serial number (UUID) and a random pin assigned. This information isaccessible via a barcode on the outside of the package and from an NFC read (Similar to apple pay or google pay type of contact with the back of the phone. The NFC read will wake up the AION TempShield™ from deep sleep and initiate the pairing. Once the initial Bluetooth contact has beenmade the mobile application will present the 6-digit pairing number that the user must type in.
Once this is done the mobile device will go into operational mode and send out temperature every five minutes. The Mobile app will look for temperature every five minutes with appropriate guard bands. Every 4hours the mobile application will request a full data offload from the AION TempShield™ to collect previous data that was not collected from the AION TempShield™.

The AION TempShield Application communicates with the AION Core (Cloud monitoring service). This service will provide NIH recommendations for fever to the shield to provide indications (alerts)in the data for visualization for the User. There is no PHI stored in the AION cloud.

The application has a home screen that displays the last read temperature. The application allows the user to put in activities, to view historical temperature history, and to select time windows to display data. For example: the application will allow the user to only view data for the past 12 hours. The total viewable data window is 48 hours.

The application in the settings window will allow the user to view the UUID and will allow the user to replace the AION TempShield™ with another one. The Application will provide the user with thepercentage of charge left in the device (battery life indication). When the battery life reaches 10% of charge left, the application will provide an alert that the user should get a new AION TempShield™ (there will be approximately 1 week of continuous life available. At 5% life the notifications are once per two hours to replace the shield.

The AION TempShield™ requires that the user place medical grade silicone tape to hold the AION TempShield™ in place. The AION TempShield™ is provided with a patient user guide. The end user is expected to provide a mobile device (Android 10 or greater or iOS 11 or greater). The iPhone 6 and earlier will not work. The mobile device must have an NFC reader to fully operate.

Specifications and Configurations

The AION TempShield™ is < 8 grams is approximately 42mm in diameter and 3.2 mm in height. The device is single-person use and is held in place via off the shelf silicone tape. The device is IP x57 dust and waterproof. And the operating range is from 77.0F (25C) to 109.4F (43C) degrees.

5. INDICATIONS FOR USE

The AION TempShield™ is a battery powered wearable thermometer intended for continuous measurement of human body temperature on the upper chest via wireless communication to a smart device application. AION TempShield™ is intended for single-use and for persons aged 1 year and older in either healthcare facilities or home environments.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device was designed to provide the benefit of continuous temperature measurement that allows wireless communication to smart devices for monitoring.

The subject device and predicate are both single use devices used for continuous temperature monitoring at healthcare facilities (hospital or hospital type facilities) and in home environments. Both devices are placed on the patient's upper chest and based on the principle that temperature measured at the skin surface can be extrapolated to the body temperature. The subject device and primary predicate are both disposable with identical accuracy of +/- 0.1°C, conforming to ISO 80601-2-56, using a thermistor sensor, supporting mobile device compatibility, utilizing Bluetooth, and powered by a CR2016 Li-Mag coin cell battery, while the secondary predicate is non-disposable and has a slightly broader accuracy range for certain temperatures.

The subject device uses Near Field Communications (NFC) RFID for power on and pairing key, is smaller and weighs less, and has a longer battery life. These differences do not affect the safety or effectiveness of the device.

7. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Technological Characteristic	**Subject Device AION TempShield™**	**Primary Predicate Device iTempshield K232010**	**Secondary Predicate Device Fever Scout K181013**	**Comparison**
Indications for Use	The AION TempShield™ battery powered wearable thermometer intended for continuous measurement of human body temperature on the upper chest via wireless communication to a smart device application. AION TempShield™ is intended for single-use and for persons aged 1 year and older in healthcare facilities and home environments.	The iTempShield battery powered wearable thermometer intended for continuous measurement of human body temperature on the upper chest via wireless communication to a smart device application. iTempShield is intended for single-use and for persons older than 5 years in healthcare facilities and home environments.	The wireless Fever Scout continuous monitoring thermometer is a non-invasive and re-usable electronic device for home use. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.	The Subject Device and Primary Predicate have almost identical indications for patient population range expanded to cover 1 year and older (compared to 5 years and older). The Secondary Predicate Device has population range that covers 29 days and older. The indications for use for all devices include wireless continuous measurement, home use for measurement of body temperature.
Placement Location	Upper Chest	Upper Chest	Armpit	The Subject Device and Primary Predicate are used on the Chest and the Secondary Predicate is used on Armpit.
Classification Regulation / Product Code	21 CFR 880.2910 / FLL	21 CFR 880.2910 / FLL	21 CFR 880.2910 / FLL	IDENTICAL
Regulation Description	Clinical electronic thermometer	Clinical electronic thermometer	Clinical electronic thermometer	IDENTICAL
Principle of Operation	Based on the principle that the temperature measured at the skin surface can be extrapolated to the body temperature. The sensor within the subject device detects the heat and measures the temperature using a resistance that changes with heat.	Based on the principle that the temperature measured at the skin surface can be extrapolated to the body temperature. The sensor within the predicate device detects the heat and measures the temperature using a resistance that changes with heat.	Utilizes e-skin technology with sensors within the device to detect heat and measure temperature using a resistance that changes with heat.	IDENTIAL
Laboratory Accuracy	± 0.1C in the range of 25C to 43C	± 0.1C in the range of 25C to 43C	+/- 0.1C from 37C to 39C	IDENTICAL between Subject Device and Primary Predicate.

			+/- 0.2C from 35C to 37C and 39C to 42C	The Secondary Predicate has a slightly wide range for some temperatures.
Validation Method	Conforms to ISO 80601-2-56	Conforms to ISO 80601-2-56	Conforms to ASTM E1112-2000 (standard specification for electronic thermometer for intermittent determination of patient temperature)	IDENTICAL Both standards are recognized by FDA as valid standards for electronic thermometers.
Type of Use (sensor)	Disposable	Disposable	Reusable	Subject device is identical to primary predicate while the secondary predicate is reusable.
Type of Sensor	Thermistor	Thermistor	Thermistor	IDENTICAL
Temperature Measurement Intervals	Transmits Maximum once per 5 minutes and Minimum once per 240 minutes.	Transmits Maximum once per 5 minutes and Minimum once per 240 minutes.	Transmit every 15 seconds	Temperature measurement intervals are shorter for the secondary predicate device.
Wireless Supported Devices	Mobile (Android, Apple)	Mobile (Android, Apple)	Mobile (Android, Apple)	EQUIVALENT – both devices are supported by Android and Apple. The devices are supported by the technologies for the company (i.e. iTempShield with AION shield App, and TempShield with AION TempShield App).
Wireless Type	Bluetooth LE 4.2 NFC RFID for power ON and pairing	Bluetooth LE 4.2 NFC RFID for power ON and pairing	Bluetooth BLE	IDENTICAL
Type of Application	Wearable	Wearable	Wearable	IDENTICAL
Overall Dimension	Diameter 42mm Thickness 3.2mm	Diameter 42mm Thickness 3.2mm	Size 61mm x 41mm* Thickness 5.5mm*	The subject device is identical to the primary predicate device. However, it is smaller than the secondary predicate.
Weight	5 grams	5 grams	7.3g*	The subject device is identical to the primary predicate device. However, it is smaller and weighs less than the secondary predicate.
Biocompatibility	Conforms to ISO	Conforms to ISO	Conforms to ISO	IDENTICAL

	10993-1, 5, 10	10993-1, 5, 10	10993-1, 5, 10	
Power Source	Internal Battery (Lithium Coin Cell) 3V	Internal Battery (Lithium Coin Cell) 3V	Internal Battery (Lithium Rechargeable) 3V	IDENTICAL
Battery Life	2160 hours (90 days) of continuous run time	1440 hours (60 days) of continuous run time	168 hours (7 days) of continuous run time*	The battery life is substantially longer for the subject device.
Electrical Safety	Conforms to IEC 60601-1	Conforms to IEC 60601-1	Conforms to IEC 60601-1	IDENTICAL
Electromagnetic Compatibility	Conforms to IEC 60601-1-2	Conforms to IEC 60601-1-2	Conforms to IEC 60601-1-2	IDENTICAL
Storage / Transport Temperature	32F to 86 (0C to 30C)	32F to 86 (0C to 30C)	50F – 104F*	The Storage temperature for the Subject device and primary predicate are identical. The range for the secondary predicate includes higher temperatures.
Storage / Transport Humidity	45% RH to 75% RH (non-condensing)	45% RH to 75% RH (non-condensing)	15-85% RH*	The storage RH range is identical between the subject device and primary predicate. The storage range for the secondary predicate is wider. The Storage humidity range for the subject device was developed to match the instructions provided by the battery manufacture. This is only applicable to the storage conditions and will not affect the user.
Operating Temperature	10C to 40C	10C to 40C	50F (10C) to 104 (40C)	Equivalent
Operating Humidity	10% RH to 95% RH (non-condensing)	10% RH to 95% RH (non-condensing)	15% to 85% RH (non-condensing)	Equivalent
Atmospheric Pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa	700 hPa to 1060 hPa*	IDENTICAL
Mode of Operation	Continuous	Continuous	Continuous	IDENTICAL

**** This information is from the Fever Scout Instructions for Use Manual and from the 510(k) Summary K162137***

Design

The iTempShield was cleared by FDA in August 2023 under K232010. The subject device is the same device except the name was changed to AION TempShieldTM . The primary differences between the subject device and the primary device are:

- Expanded patient population age from 5 years and older to 1 year and older.
- Expanded battery life from 60 days to 90 days.
- Changes to firmware for battery life extension

The iTempShield used the Masimo Radius T (K203215) as the predicate device. The Radius T used Fever Scout (K181013) as their predicate device. The Radius T was applied on the chest and used for 5 years and older whereas their predicate device was placed in the armpit and used for 29 months and older.
The subject device and the primary predicate device identical in all aspects of design, technology, and principles of operations with the exception of the minor differences mentioned above. The expansion of battery life and change to firmware is supported with software validation and bench testing. The expansion of the patient population age range is supported by clinical data.
The secondary predicate is being utilized to provide a predicate that has an age group similar to the age group being pursued for the AION TempShieldTM. The subject device has a longer battery life, has different anatomical placement, has different measurement intervals and is smaller in size compared to the secondary predicate.

Based on the substantial equivalence comparison and provided testing, the above differences do not impact the safety or effectiveness of the device.

Operational and Technological Characteristics

Both the subject and predicate devices are based on similar principles of operation, battery powered and use Bluetooth wireless technology to communicate data. The devices have the similar accuracy and support similar wireless devices.
The subject device and primary predicate are identical in characteristics except as mentioned with the expanded battery life, firmware change to support the battery life expansion and expansion in patient population age range.
The subject device and the secondary predicate have similar characteristics except for measurement intervals, anatomical placement, and size.
The difference in transmission time (measurement interval) does not impact safety or effectiveness as this device is not measuring vital physiological parameters (such as heartrate or respiration). The longer battery life offers benefit to the clinician and user to allow for longer period of time for monitoring the patient. The clinical data supports that the expanded patient population range (which is similar to the secondary predicate device).

The Subject Device has the equivalent anatomical placement, indications for use (except for patient age range), principle of operation, compliance to test standards with the updated 80601 standard-1, single use, wearable, use of thermistors, disposable, battery powered, wireless communication to smart devices using Bluetooth, and continuous mode of operation as the primary predicate device. The main differences are between patient population age range, battery life expansion and firmware change to support battery life expansion.

Summary of Similarities and Differences

The Subject Device has similar characteristics as the secondary predicate which exception of:

- Subject device has faster measurement intervals.
- Subject device is smaller and weighs less than the secondary predicate.
- Subject device and primary predicate are placed on the chest, whereas the secondary predicate is placed in the armpit.

The minor differences in design and technology do not present an increased risk of safety and effectiveness of the device nor do they raise different questions of safety and effectiveness as supported by the compliance testing to the electrical safety IEC 60601-1 series standards, laboratory and clinical accuracy testing to the IEC 80601-2-56, biocompatibility testing to the ISO 10993 series standards as well as the performance bench testing and human factors evaluation.

8. PERFORMANCE TESTING

The following standards were used for testing of the subject device:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60529
- IEC 60601-1-6
- IEC 62366
- IEC 60601-1-11
- ISO 80601-2-56

Biocompatibility evaluation for the following contact classification was conducted:

- For Contact Type: Surface Skin
- Contact Duration: Up to 90 days
- Classification: C (Intact Skin, Greater than 30 days)

The classification and endpoints: cytotoxicity, skin irritation, and sensitization, associated with this classification have been assessed in accordance with:

- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-23

The following FDA guidance documents were utilized:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Issued May 2005

- FDA Guidance on the content of premarket notification 510(k) submissions for clinical electronic thermometers – March 1993

SUMMARY OF TESTING		
Standard	**Description of Test**	**Results**
Electromagnetic Compatibility, Electrical Safety, and Home Healthcare Safety		
IEC 60601-1:2012	**Electrical Safety** Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	All applicable requirements were tested and passed.
IEC 60601-1-2:2014	**Electromagnetic Disturbance** Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic disturbances – Requirements and Tests	All applicable requirements were tested and passed.
IEC 60601-1-11:2015	**Safety for Home Healthcare Environment** 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	All applicable requirements were tested and passed.
Ingress Testing		
IEC 60529:2013/COR1:2019	**Ingress** Degrees of protection provided by enclosures IP57 The testing include dust penetration and water ingress.	All applicable requirements were tested and passed.
Usability Testing / Human Factors		
IEC 60601-1-6:2010 / AMD1:2013	**Usability** Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability	All applicable requirements were tested and passed.
IEC 62366-1:2015	**Usability** Medical Device – Application of Usability Engineering to Medical Devices	PASS – all applicable requirements were tested and passed.
No related standard	**Usability**	PASS – The original study included 137 participants 5 years and old, the addendum study included 39 participants ages 1-4 years. All tested passed and verified accurate body temperature.
PERFORMANCE BENCH TESTING		
ISO 80601-2-56:2017	**Clinical Thermometer Performance** Medical Electrical Equipment – Part 2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement	All applicable requirements were tested including laboratory accuracy and passed

No related standard	**Bluetooth Range Testing**	PASS – the testing concluded the mobile app received temperature data from the AION TempShield™ at 0.1m and 10m away from the phone.
No related standard	**Disinfection Resistance Testing**	PASS – the testing concluded that the AION TempShield™ continued to send temperature data after 90 cleanings using disinfectant wipes. There were no visible defects on the device.
No related standard	**Operational Temperature Range Testing**	PASS – The AION TempShield™ continued to function andsend temperature data at every temperature within the range.
No related standard	**Battery Notification Test**	PASS – The AION TempShield™ transmits proper battery percentage depletion, displays raw temperaturesin DTM mode and passes encrypted data.
No related standard	**Product Life / Accelerated Aging Test**	PASS – The devices were found to be fully functional at end of storage test (23 days at 70C) with no physical defects observed. The devices were found to be functional and transmitted data after 15 days at 60C.
Software / Firmware Verification & Validation		
No related standard	**Software Verification & Validation Testing** Mobile Application Verification and Validation	PASS – The V&V testing demonstrated that the AION TempShield Mobile Appmeets specified requirements and functions as intended.
No related standard	**Software Verification & Validation Testing** AION TempShield™ Firmware RequirementsV&V Report	PASS – The V&V testing demonstrated that the AION TempShield™ firmware meets specified requirements and functions as intended.
Biocompatibility Testing		
ISO 10993-1:2016	**Biocompatibility** Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	All applicable requirements were tested and passed

ISO 10993-5:2009	**Biocompatibility - Cytotoxicity** Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	The test article showed no evidence of causing cell lysis or cytotoxicity to L-929 cells. The test article meets the requirements for the test.
ISO 10993-10: 2021	**Biocompatibility - Sensitization** Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested.
ISO 10933-23: 2021	**Biocompatibility - Irritation** Biological Evaluation of Medical Devices – Part 23: Tests for Irritation	There was no erythema and no edema on the skin of the animals treated with the test article. The primary irritation index for the test article was calculated to be 0.0. The response of test article was categorized as negligible.
Wireless Testing / Cybersecurity		
FCC Part 15 and Part 2	**Wireless Testing** Testing to FCC part 2 and part 15	PASS – The FCC wireless testing passed all applicable requirements.
No related standards	**Cybersecurity**	PASS – The device passed all applicable cybersecurity testing.
No related standards	**Coexistence Study**	PASS – The device passed applicable coexistence with several wireless active products operating.

9. SAFETY AND EFFICACY

The subject device has been tested to and complies with applicable consensus standards. Additionally, the software contained within the medical device has been developed and tested inaccordance with FDA guidance for software. All of the testing passed and there were no identified issues that would impact the safety, performance, or efficacy of the subject device.

10. CONCLUSION

The information presented supports substantial equivalence of the AION TempShield™ to the predicatedevice based on the intended use and similarities in design, principles of operation and performance specifications.

The company concluded that based on testing, compliance to consensus standards, the indicationsfor use, technological characteristics, and comparison to predicate device the AION TempShield™ is substantially equivalent to the predicate device and is as safe and effective for the intended use.