August 4, 2023

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

Re: K232010
Trade/Device Name: iTEMPSHIELD
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 3, 2023
Received: July 6, 2023

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 (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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232010

Device Name
iTempShield

Indications for Use *(Describe)*
The iTempShield 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. iTempShield is intended for single use and for persons older than 5 years in healthcare facilities and 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.

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K232010 - 510(k) Summary

Third Party Traditional 510(k)

Idion iTEMPSHIELD

1. SUBMITTER/510(K) HOLDER

AION Biosystems Inc.

12 Plymouth Road

Darien, CT 06820

Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC) Email:

jazary@aztechregulatory.com or jazary@erols.com Telephone: (203) 242-6670

Date Prepared: August 4, 2023

Reason for 510(k): New device

2. DEVICE NAME

Proprietary / Trade Name:	iTEMPSHIELD
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

Device Name	Manufacturer	510(k) Number
Radius T wearable thermometer	Masimo Corporation	K203215

4. DEVICE DESCRIPTION

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

The iTempShield can be worn for up to 60 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 IDION account.

The temperature measurements are in degrees Fahrenheit (F).

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 IDION Shield 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 iTempShield is shipped in a shelf mode power condition (4uA) and can be on the shelf for 14 months before the battery is depleted below the 60-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 iTempShield. Each iTempShield has a unique serial number (UUID) and a random pin assigned. This information is accessible 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 iTempShield from deep sleep and initiate the pairing. Once the initial Bluetooth contact has been made 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 iTempShield to collect previous data that was not collected from the iTempShield.

The Idion Application communicates with the Idion 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 Idion 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 iTempShield with another one. The Application will provide the user with the percentage 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 iTempShield (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 iTempShield requires that the user place medical grade silicone tape to hold the iTempShield in place. The iTempShield is provided with a patient user guide. The end user is expected to provide a mobile device (Android 10 or greater or iPhone SE 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 iTempShield 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 iTEMPSHIELD 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. iTEMPSHIELD is intended for single-use and for persons older than 5 years in healthcare facilities and 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. Both devices have an accuracy of +/- 0.1C, conform to ISO 80601-2- 56, are disposable, use a thermistor sensor, have supported use on mobile devices, use Bluetooth, and are powered using a CR2016 LI-Mag coin cell battery.

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 iTempshield**	**Primary Predicate Masimo Radius T K203215**	**Comparison**
Indications for Use	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.	Radius T wearable thermometer is intended for single-use, continuous noninvasive measurement of body temperature on the upper chest via wireless communication to a smart device application or compatible patient monitor (i.e., Masimo Root, Masimo Rad-97). The Radius T is indicated for single-use, continuous body	EQUIVALENT – The indications for use are equivalent between the devices. The predicate indications includes communication to a patient monitor whereas the subject device does not include that.

		temperature measurements of persons 5 years of age or older in hospitals, hospital type facilities and home environments.	
Placement Location	Upper Chest	Upper Chest	IDENTICAL
Classification Regulation / Product Code	21 CFR 880.2910 / FLL	21 CFR 880.2910 / FLL	IDENTICAL
Regulation Description	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.	IDENTICAL
Laboratory Accuracy	+/- 0.18F (0.1C) from 77.0F (25C) to 109.4F (43C)	+/- 0.1C from 25C to 43C	IDENTICAL
Validation Method	Conforms to ISO 80601-2-56	Conforms to ISO 80601-2-56	IDENTICAL
Type of Use (sensor)	Disposable	Disposable	IDENTICAL
Type of Sensor	Thermistor	Thermistor	IDENTICAL
Temperature Measurement Intervals	Transmits once per 5 minutes	Transmits every 60 seconds	Temperature measurement intervals are shorter for the predicate device.
Wireless Supported Devices	Mobile (Android, Apple)	Mobile (Android, Apple), Masimo Patient Monitoring Devices	EQUIVALENT – both devices are supported by Android. The devices are supported by the technologies for each company (i.e.. Radius T and Masimo Patient Monitoring Device, and iTempShield with App).
Wireless Type	Bluetooth BLE NFC RFID for power ON and pairing	Bluetooth BLE	IDENTICAL – Both devices use Bluetooth. Device is better with NFC pairing (because user friendly)
Type of Application	Wearable	Wearable	IDENTICAL
Overall Dimension	Diameter 42mm Thickness 3.2mm	Length 127mm Width 127mm Thickness 12.7mm	The subject device is smaller.

Weight	5 grams	30 grams	The subject device is smaller and weighs less.
Biocompatibility	Conforms to ISO 10993-1, 5, 10	Conforms to ISO 10993-1, 5, 10	IDENTICAL
Power Source	Internal Battery (Lithium Coin Cell) 3V	Internal Battery (Lithium Coin Cell)	IDENTICAL
Battery Life	1440 hours (60 days) of continuous run time	Minimum of 8 days (192 hours) of continuous run time	The battery life is substantially longer with the subject device.
Electrical Safety	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	IDENTICAL
Storage / Transport Temperature	32F (0C) to 86F (30C)	-20C to 50C (-4F to 122F)	The Storage temperature range was reduced to match the instructions provided be the battery manufacture. This is only applicable to the storage conditions and will not affect the user.
Storage / Transport Humidity	40% RH to 75% RH (non-condensing)	10% RH to 95% RH (non-condensing)	The Storage humidity range was reduced 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	50F (10C) to 109.4F (43C)	10C to 40C	Equivalent
Operating Humidity	10% to 95%	10% to 95%	IDENTICAL
Atmospheric Pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa	IDENTICAL
Mode of Operation	Continuous	Continuous	IDENTICAL

The Subject Device has the equivalent anatomical placement, indications for use, principle of operation, compliance to FDA recognized consensus standards, single use, wearable, use of thermistors, disposable, battery powered, wireless communication to smart devices using Bluetooth, and continuous mode of operation.

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 60 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 / Summative Study**	PASS – the summative usability evaluation included 45 participants consisting of healthcare professionals, adult patient/caregivers, and adolescent patients. The conclusion of the study was that the subject device is safe, efficient to use, and provides ease of use to the user / operator.
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 iTempShield at 0.1m and 10m away from the phone.
No related standard	**Disinfection Resistance Testing**	PASS – the testing concluded that the iTempShield continued to send temperature data after 60 cleanings using disinfectant wipes. There were no visible defects on the device.
No related standard	**Operational Temperature Range Testing**	PASS – The iTempShield continued to function and send temperature data at every temperature within the range.
No related standard	**Battery Notification Test**	PASS – The iTempShield transmits proper battery percentage depletion, displays raw temperatures in 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 IDION Shield Mobile App meets specified requirements and functions as intended.
No related standard	**Software Verification & Validation Testing** iTempShield Firmware Requirements V&V Report	PASS – The V&V testing demonstrated that the iTempShield 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 in accordance 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 iTempShield to the predicate device 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 indications for use, technological characteristics, and comparison to predicate device the iTempShield is substantially equivalent to the predicate device and is as safe and effective for the intended use.