November 30, 2018

Wello, Inc
Alan C. Heller
Chairman and CEO
800 East Campbell Road, Suite 202
Richardson, Texas 75081

Re: K180298
Trade/Device Name: welloStationX
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 29, 2018
Received: November 29, 2018

Dear Alan C. Heller:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180298

Device Name
welloStationX

Indications for Use *(Describe)*
The welloStationX is a non-contact infrared forehead thermometer intended for use to measure the body temperature of individuals over 5 years of age and older. The welloStationX can be used by medical professionals or laypersons in any public or private indoor facility with environmental conditions maintained within 15°C to 28°C (59°F to 82.4°F), 20 - 70% RH non-condensing.

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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510(k) SUMMARY

510(k) Number: K180298

Submitter: Wello Inc.
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Contact Person:
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Chairman and CEO
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Date Prepared: November 30, 2018

Proposed Device	Manufacturer:	Wello, Inc.
	Trade Name:	welloStationX™
	Common Name:	IR Thermometer
	Classification Name:	Clinical Electronic Thermometer
	Product Code	FLL
	Regulation:	21 CFR 880.2910, Thermometer, Electronic, Clinical
	Classification:	Class II
Predicate Device:	Clearance:	K131771 dated Oct 07, 2013
	Manufacturer:	Thermomedics, Inc.
	Trade Name:	Caregiver Professional Clinical Thermometer
	Common Name:	IR Thermometer
	Classification Name:	Clinical Electronic Thermometer
	Product Code	FLL
	Regulation:	21 CFR 880.2910, Thermometer, Electronic, Clinical
	Classification:	Class II

Device Description: The welloStationX uses an infrared sensor to measure human body temperature. It is offered as a desktop or kiosk model.

The WSX consists of a display screen with an IR camera mounted to the top of the display screen. The display screen provides instructions to subjects being screened. Both the kiosk and desktop model operate in the same manner. The subject reads and follows the on-screen instructions to position themselves in the correct location approximately 10 inches from the WSX. In 3 seconds, the WSX provides output of the subject's core body temperature.

Each temperature reading will be output with either a green background or a red background. Temperature displayed with a red background will also include a prompt to obtain a second temperature evaluation using an alternate method. The facility can select the action threshold or use the default threshold above which the reading will be displayed with a red background. Users can receive email alerts for any subject with a temperature reading displayed with a red background. For some features, an active internet connection is required.

Indications for Use Statement:

The welloStationX is a non-contact infrared forehead thermometer intended for use to measure the body temperature of individuals over 5 years of age and older. The welloStationX can be used by medical professionals or laypersons in any public or private indoor facility with environmental conditions maintained within 15°C to 28°C (59°F to 82.4°F), 20 - 70% RH non-condensing.

Summary of Technological Characteristics:

Device & Predicate Device(s):	K180298	**K131771**	**Conclusion**
General Device Characteristics			
Product Code(s)	FLL	FLL	Identical
Regulation(s)	880.2910	880.2910	Identical
Rx/OTC	OTC	OTC	Identical
Features	Temperature & Photo Recall Multiple Modes °F/°C scale Date and Time Error Messages Wi-Fi/Ethernet Connectivity Online Storage/Notifications	Temperature Recall Multiple Modes °F/°C scale Date and Time Error Messages Sleep/Auto Shutoff Low Battery Indicator	Different
Operational Mode(s)	Online Mode Offline Mode Standalone Mode	Body Temperature Mode Surface Temperature Mode Room Temperature Mode	Different
Technology	Non-contacting IR sensor; Freestanding	Non-contacting IR senor; Handheld	Different
Accessories	Thermal Printer (optional) Mounting Hardware WelloCloud/welloinc.net (optional)	Protective Cap Wall Mount (optional) Security Tether (optional)	Different
Displayed Temperature Range(s)	Body: 95°F to 107.6°F (35°C to 42°C) "Invalid Measurement" Displayed if temperature appear outside of the body temperature range.	Body: 94°F to 108.0°F (34.4°C to 42.2°C) "Lo" Temperatures <94°F (34.4°C) "Hi" Temperatures >108°F (42.2°C) "LOW Temps" Displayed temperatures appear to be too low Surface: 32°F to 140°F (0°C to 60°C)	Different
Displayed Accuracy	±0.2°C (±0.4°F)	96.8/102.2°F ±0.4°F (36/39°C ±0.2°C) 71.6/96.7°F ±0.5°F (22/35.9°C ±0.3°C) 102.3/108.0°F ±0.5°F (39.1/42.2°C ±0.3°C) Not specified below 71.6°F (22°C)	Different

Power Source	Mains 100-240 V / 50-60 Hz NO BATTERIES	Two 1.5v "AA" Alkaline Batteries	Different
Dimensions	Desktop: 13.5 W x 13.25 H x 7 D (in) Kiosk: 19.5 W x 57.5 H x 14.5 D (in)	150 L x 48.48 W x 55.16 H (mm)	Different
Field of View	±5° cone angle	±8° cone angle	Different
Measuring Distance	12 to 13 inches	0.5 to 2.0 inches	Different
Calibration	Factory Calibration Only Start-up auto calibration	User Calibration Mode	Different
Reading Time	3 sec 10 sec between measurements	1-2 sec 20 sec between measurements	Similar
Start-up / Acclimation Time	Start-up: 30 seconds includes self-test and calibration	Patient Acclimation: 20 minutes Thermometer Acclimation: 20 minutes	Different
Cleaning Surface	Wipe with IPA	Wipe with IPA/Detergent	Identical
Operation Conditions	15°C to 28°C (59°F to 82.4°F) 20% to 70% RH non-condensing	50°F to 104°F (10°C to 40°C) ≤ 85% RH	Similar
Storage Conditions	-20°C to 50°C (-4°F to 122°F)	-4°F to 140°F (-20°C to +60°C)	Similar
Technical Specifications	ASTM E1965-98	ASTM E1965-98	Similar
EMC/Electrical Safety	IEC 60601-1-2	IEC 60601-1-2	Identical

The WSX shares technological characteristics with the predicate device. The proposed device also has some differences in technological characteristics from those of the predicate device. Differences in the technological characteristics have been verified and validated as part of performance testing and do not impact the safety, effectiveness, or substantial equivalence of the device.

Both the WSX and the predicate are indicated for OTC use for professionals and laypersons for measuring body temperature, utilize an IR sensor for non-contact temperature measurement, utilize LCD screens for output in either °C or °F, and utilize software to function.

Differences in function exist between the proposed and predicate devices. The predicate includes non-medical (Room and Surface) temperature measurements that the WSX does not offer. The body temperature ranges differ as does the accuracy. The WSX has the ±0.2°C (±0.4°F) accuracy across all temperatures (95°F to 107.6°F) while the predicate has ±0.2°C (±0.4°F) accuracy across a limited range (96.8°F to 102.2°F) with ±0.3°C (±0.54°F) accuracy over the remaining ranges (94.0°F to 96.7°F; 102.3°F to 108.0°F).

The primary differences are in the form rather than function. The WSX is freestanding (desktop or kiosk) while the predicate is hand-held, therefore the WSX is larger and utilizes AC power.

Summary of Performance Testing:

Tests were performed on the device which demonstrated that the device performs comparably to and is substantially equivalent to the predicate device.

A Clinical accuracy validation of the welloStationX® based on ISO 80601-2-56 was conducted in 110 males and females aged 5 years of age and older. Temperature was measured using the WelloStationX and a Welch Allyn SureTemp oral thermometer. Each measurement was recorded by a trained technician following the instructions for use in the respective device labeling. The validation study

demonstrated that the clinical accuracy of the welloStationX® was equivalent to the oral thermometer and reported values for the predicate device.

Additional tests included verification/validation testing to internal functional specifications (including software) and side-by-side bench accuracy testing of the new device and the predicate device. Documentation was provided demonstrating compliance to FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software hazards. Testing was also conducted for compliance to:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366, Medical Devices - Application of usability engineering to medical devices
- IEC 62304, Medical device software -- Software life cycle processes
- ASTM E1965 – 98, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- 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.

Conclusion: *Wello Inc* considers the *welloStationX*™ to be substantially equivalent to the predicate device listed above. This conclusion is based on the non-clinical data that demonstrates the device performs as intended in the specified use conditions and on the similarities in intended use, principles of operation, and functional design.