October 25, 2018

E-Care Technology Co., Ltd.
Mr. K.Y. Ko
Engineer
8F-11, No. 35, Hsin-Tai Road
Chubei City, Hsinchu 302 Taiwan

Re: K170723
Trade/Device Name: Swaive Thermometer, Model: SWT1A
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 20, 2018
Received: September 24, 2018

Dear Mr. K.Y. Ko:

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,

Alan M. Stevens -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)*
K170723

Device Name
Swaive Thermometer, Model: SWT1A

Indications for Use *(Describe)*
This device is an electronic clinical thermometer (infrared ear thermometer) to measure and monitor body temperature from auditory canal for people of all ages in a home set environment.

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

1. **Submitter Information:**

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8F-11, No.35, Hsin-Tai Road
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Taiwan
Contact: Mr. K.Y. Ko
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Tel:886-3-5534996
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Date Prepared: October 25, 2018

2. **Name of Device:**

Trade name: Swaive Thermometer, Model: SWT1A
Common name: Infrared ear thermometer
Classification name: Thermometer, electronic, clinical (21 CFR 880.2910, Product code: FLL)

3. **Predicate Device:**

AViTA Infrared Thermometer with Bluetooth, Model no.: TS28B (510(k) no.: K110559)

4. **Device Description:**

The Swaive Thermometer SWT1A is a hand-held, battery-powered electronic thermometer which uses an infrared sensor to detect body temperature from the auditory canal. It is an infrared ear thermometer with disposable probe cover. It measures the thermal infrared radiation emitted from the tympanic membrane and the surrounding tissue by the sensor inside the probe. The electronic signal of sensor is amplified, calculated, converted into temperature value, and then displayed on LED board by the electronic circuit inside. It only takes a few seconds for the whole measurement process.

Besides the temperature measurement circuit, a Bluetooth circuit is embedded in SWT1A to transmit the temperature value to smart phone via the specified App "Swaive Thermometer". This App only stores the temperature value on the smart phone if needed and has no clinical intention. SWT1A is a stand-alone device. It measures ear temperature and displays on its LED display with or without connecting with smart phone.

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5. Indications for Use:

This device is an electronic clinical thermometer (infrared ear thermometer) to measure and monitor body temperature from auditory canal for people of all ages in a home set environment.

6. Comparison of Technology Characteristics with the Predicate Device:

Item	Subject Device: Swaive Thermometer Model: SWT1A	Predicate Device: AViTA Infrared Thermometer with Bluetooth Model: TS28B	Comparison
510 (k) #	K170723	K110559	N/A
Thermometer type	Infrared ear thermometer with Bluetooth	Infrared ear thermometer with Bluetooth	Same
Indications for use	This device is an electronic clinical thermometer (infrared ear thermometer) to measure and monitor body temperature from auditory canal for people of all ages in a home set environment.	This device is an infrared thermometer intended for the intermittent measurement of human body temperature for people of all ages.	Similar
Sensor	Infrared (thermopile+ thermistor)	Infrared (thermopile+ thermistor)	Same
Principal of operation	This thermometer uses an infrared sensor to detect the infrared radiant from auditory canal and convert into electrical signal for calculation of auditory canal temperature. The temperature value can be transferred to smart phone via Bluetooth circuit.	This thermometer uses an infrared sensor to detect the infrared radiant from auditory canal and convert into electrical signal for calculation of auditory canal temperature. The temperature value can be transferred to smart phone via Bluetooth circuit.	Same
Measurement range	33.3~42.2℃ (92.0~108.0°F)	34~43℃ (93.2~109.4°F)	Similar

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Accuracy	±0.2℃ (0.4℉): 33.3~42.2℃ (92.0~108.0℉)	±0.2℃ (0.4℉): 36~39℃ (96.8~102.2℉) ±0.3℃ (0.5℉): 34~36℃ & 39~43℃ (93.2~96.8℉ & 102.2~109.4℉)	Complies with ASTM E1965-98
Operating environment	16-40℃ (60.8-104℉) ≤95% Relative humidity	16-40℃ (60.8-104℉) ≤95% Relative humidity	Same
Storage environment	-20℃~50℃ ≤95% Relative humidity	-20℃~50℃ ≤95% Relative humidity	Same
Display resolution	0.1℃ or ℉	0.1℃ or ℉	Same
Performance	Complies with ASTM E1965-98	Complies with ASTM E1965-98	Same
memory	none	10 sets	Different
Data transmission	Bluetooth	Bluetooth	Same
Battery	2 x AA	2 x AAA	Similar
Disposable probe cover	yes	no	Different
Materials	Patient contacting materials include LDPE (probe cover) and ABS (device housing)	Patient contacting material includes ABS (device housing)	Different
Biocompatibility	Complies with ISO 10993-1, ISO 10993-5 & ISO 10993-10	Complies with ISO 10993-1, ISO 10993-5 & ISO 10993-10	Same
Safety	Complies with IEC60601-1	Complies with IEC60601-1	Same
EMC	Complies with IEC60601-1-2	Complies with IEC60601-1-2	Same

The differences between 2 devices are:

1. The memory of subject device has zero, but the predict K110559 has 10 memories. The devices measure temperature independently every time. The previous measurement will not affect new measurement and whether the device stores temperature reading does not affect new measurement.

2. The subject device uses disposable probe cover, but the predicate K110559 does not, and they have different patient-contacting materials. The subject device uses a disposable probe cover to provide a sanitary barrier between a subject and the probe. The non-clinical and clinical tests demonstrate the performance of this subject device using a probe cover complies with ASTM E1965-98 (2016) as the predicate device. According to ISO10993-1, the disposable probe cover has passed the relative biocompatibility tests and does not raise new biocompatibility issue.
From above discussion, the difference between these two devices does not raise any new performance issue.

7. Non-Clinical Testing:

The following non-clinical tests were conducted according to FDA recognized consensus standards or USA regulations, and software verification and validation data was completed as recommended in the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices dated May 11, 2005". All these tests results are provided in support of the substantial equivalence determination.

Standard name	Test name & report no.	result
IEC 60601-1:2005+AM1(2012) Medical electrical equipment –Part 1: General requirements for basic safety and essential performance	UT104079: IEC 60601-1: 2005+AM1(2012) test report	pass
IEC 60601-1-2 Edition 3:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	1560372R-ITCEP15V00: IEC 60601-1-2:2007 test report	pass
ASTM E1965-98:2016 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	SWT1A Performance check list Shock test, Storage test, Laboratory accuracy test,	pass
Bluetooth qualification process	Bluetooth Qualification test report	pass
FCC 47 CFR Part 15B: Radio Frequency Devices-Unintentional	EM-F140674: FCC 47 CFR Part 15B test report	pass

Radiators		
FCC 47 CFR Part 15C: Radio Frequency Devices-Intentional Radiators	1550091R-RFUSP01V00 FCC 47 CFR Part 15C test report	pass
ISO 10993-5:2009: Biological evaluation of medical devices: part 5: Tests for in vitro cytotoxicity	SDWH-M201701064-1: In vitro cytotoxicity test of probe cover SDWH-M201801942-1(E): In vitro cytotoxicity test of Swaive Thermometer, Model SWT1A	pass
ISO 10993-10, Biological evaluation of medical device – Part 10: Tests for irritation and skin sensitization.	SDWH-M201701064-2: Skin sensitization test of probe cover (1) SDWH-M201701064-3: Skin sensitization test of probe cover (2) SDWH-M201701064-4: Skin irritation test of probe cover (1) SDWH-M201701064-5: Skin irritation test of probe cover (2) DWH-M201801942-2 (E): Skin sensitization test of Swaive Thermometer, Model: SWT1A (1) DWH-M201801942-3 (E): Skin sensitization test of Swaive Thermometer, Model SWT1A (2) DWH-M201801942-4 (E): Skin irritation test of Swaive Thermometer, Model SWT1A (1) DWH-M201801942-5 (E): Skin irritation test of Swaive Thermometer, Model SWT1A (2)	pass

8. Clinical Testing:

Controlled human clinical study was conducted in accordance with ASTM E1965-98:2016. Clinical tests were conducted on the subject device SWT1A. The clinical tests evaluated 165 subjects which were divided into three group age ranges-infant (new born to 1 year), children (greater than 1 to 5 years old) and greater than 5 years old. There are more than 30 subjects for each group. The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

9. Conclusions:

The subject device SWT1A and the predicate device K110559 have similar indications for use. They use the same technology and have the same principal of operation. These performance tests demonstrate the differences between the subject device and predicate K110559 do not raise new performance question. Based on the comparison and analysis above, the subject device is substantially equivalent to the predicate device.