



Food and Drug Administration
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June 17, 2016

Withings
% Mr. Tony Chang
Wincent Consultant Co., Ltd.
No. 15, Alley 71, Cheping 1st St., Beitun District
Taichung City 406, Taiwan ROC

Re: K160544
Trade/Device Name: Withings Thermo (Model SCT01)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 9, 2016
Received: May 16, 2016

Dear Mr. Chang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160544

Device Name

Withings Thermo (Model SCT01)

Indications for Use (Describe)

The Withings Thermo (Model SCT01) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch mode over the temporal artery as the measurement site on people of all ages.

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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K160544 510(k) SUMMARY

Manufacturer's Name: Withings
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Preparation Date: June 15, 2016

Trade Name: Withings Thermo (Model SCT01)

Common or Usual Name: Withings Thermo (Model SCT01)

Classification Name and Number: Clinical Electronic Thermometer
21 CFR 880.2910
Class II
Product Code: FLL

Predicate Device: K134043
No Touch + Forehead Thermometer (Model NTF3000US)

Device Description

The Withings Thermo (Model SCT01) is a hand-held, battery powered device designed to measure human body temperature. The SCT01 device is an infrared thermometer that, when placed in contact with the user's skin over the temporal artery, measures the natural infrared energy emitted from the surface of the skin and convert it to an oral equivalent temperature.

The Withings Thermo (Model SCT01) thermometer uses a thermopile sensor for the target reading, a thermistor-like pin junction for ambient temperature readings, and a silicon lens to focus the radiated energy on the thermopile sensor. It embeds a 20x5 LEDs matrix for display of results, and also a Wi-Fi/Bluetooth module for optional usage of a smartphone application to log results

Intended Use

The Withings Thermo (Model SCT01) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch mode over the temporal artery as the measurement site on people of all ages.

Substantial Equivalence Discussion

	Subject Device: Withings Thermo	Predicate Device: No Touch+Forehead thermometer
510(k) Number	K160544	K134043
Classification	Clinical Electronic Thermometer 21 CFR 880.2910 Class II Product Code: FLL	Clinical Electronic Thermometer 21 CFR 880.2910 Class II Product Code: FLL
Intended Use	The Withings Thermo (Model SCT01) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch mode over the temporal artery as the measurement site on people of all ages.	The No Touch + Forehead Thermometer (Model NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch on the centre of the forehead as the measurement site on people of all ages.
Technological Characteristics	Infrared sensor	Infrared sensor
Measuring Method	Detection of infrared energy and use of predictive algorithms to estimate the body temperature	Detection of infrared energy and use of predictive algorithms to estimate the body temperature
Resolution	0.1°C / 0.1°F	0.1°C / 0.1°F
Clinical Accuracy	± 0.2°C on 35.5°C – 42.0°C range (± 0.4°F on 95.9°F – 107.6°F range) ± 0.3°C (± 0.5°F) outside this range	± 0.2°C on 35.5°C – 42.0°C range (± 0.4°F on 95.9°F – 107.6°F range) ± 0.3°C (± 0.5°F) outside this range
Temperature Display	Liquid Crystal Display; 3 digits (°C) and 4 digits (°F)	Liquid Crystal Display, 4 digits plus special icons
Measurement Site	Forehead: temporal artery	Forehead: centre
Operating Conditions of use (ambient temperature/ humidity)	10°C – 40°C (50 °F – 104 °F) 15% ≤ RH ≤ 95%	15 °C – 40 °C {59 °F – 104 °F }
Storage Conditions (temperature/ humidity/air pressure)	-25°C (-13°F) to +55°C (131°F) 15% ≤ RH ≤ 95% 200 hPa ≤ RH ≤ 1060 hPa	-25 °C(-13 °F) to 60 °C(140 °F) 15% ≤ RH ≤ 95% 700 hPa ≤ RH ≤ 1060 hPa
Measuring Range	35°C – 43.2 °C (95°F –109.8°F)	34.4 °C – 42.2 °C (93.9 °F -108 °F)
Power Requirements	2 AAA Batteries	2 AA Batteries
Wireless Communication	Bluetooth, Wi-Fi (never active during body temperature determination)	none
Display	LED screen display	Liquid Crystal Display
Battery Life	Up to 2 years	Up to 1000 measurements
Automatic Switch Off	30 seconds	60 seconds
Size	L = 116 mm (4.57 in.) x Diameter=33.2mm (1.31 in.)	L = 148 mm (5.83 in.) x Diameter=50mm(1.97in)
Weight	Approx. 75g (battery included) – 0.165lbs.	3.51oz. (with battery), 2.72oz. (w/o battery)
Life Cycle	5 years	3 years
Accessories	Protective scanner cap, instruction manual	Protective scanner cap, instruction manual

Performance Testing

According to the device features, the testing for the following standards were considered required for the device:

- The International Standard ISO 80601-2-56: 2012; Medical Electrical equipment – Part 2-56: Particular requirement for the safety and essential performance of clinical thermometer for body temperatures measurement.
- The International Standard ANSI/AAMI ES 60601-1: 2005 – Safety of medical device; Electrical equipment – General safety.
- The International Standard IEC 60601-1-2: 2007; Medical Electrical equipment – Safety – Electromagnetic Compatibility.
- The International Standard IEC 60601-1-11: 2010; Medical Electrical equipment – Part 1-11: general requirements for basic safety and essential performance – collateral standard: requirement for medical electrical equipment and medical electrical system used in the home healthcare environment.
- International Standard ISO 10993-1: 2009; Biological evaluation of medical devices – Part 1: Guidance on selection of tests.
- International standard ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- International standard EN/ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device. Therefore, we consider that the compliance of standards and software validation included in our submission is adequate for the determination of substantial equivalence.

Clinical Tests

The clinical testing was conducted for the accuracy of body temperature measurement between Withings Thermo (Model SCT01) and Braun NTF3000US according to the requirement set out on ASTM 1965: 2009 standard. The test result indicates that the deviation of temperature measurement deviation between Withings SCT01 and Braun NTF3000US is within acceptable range of the performance requirement of ISO 80601-2-56.

Discussion of Differences

The indications for use of the predicate device indicate the location of contact as the center of the forehead whereas the subject device specifies the temporal artery. The subject device has been validated for this more specified location through performance testing to be substantially equivalent to a “forehead” contacting thermometer.

The technological characteristics and operating principles of Withings Thermo (SCT01) thermometer are essentially similar to the predicate device. Especially, they have same intended use, same measuring method (detection of infrared energy), same sensor type, and similar clinical accuracy. They also have

close to similar operating range, measurement range and storage conditions. The most notable differences are:

- Measurement over the temporal artery uses the exact same principle and technology as measurement over the center of the forehead, and are based on similar underlying physiological characteristics. The temporal artery is a well-known candidate site for temperature measurement, and this difference only results in an adjustment of the predictive algorithm parameters. This was validated through the clinical testing.
- The wireless communication module, as documented in the software description, will never be active while the device is performing or displaying a measurement. As a result, the optional app display function is an additional feature that does not interfere in anyway with the functions, safety and usage of the SCT01 device as a standalone thermometer. This was validated through performance testing, including conformance with the relevant ISO Standards and software validation.

On the basis of the comparison between the two devices and discussion of their differences as well as the discussion of clinical and non-clinical test validation, we demonstrate that the Withings SCT01 and Braun NTF3000US are substantially equivalent.

Conclusions

The Withings Thermo (Model SCT01) has the same intended use and the similar technological characteristics as the cleared devices. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models do not raise new questions of safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, we conclude that the Withings Thermo (Model SCT01) and Braun No Touch + Forehead Thermometer NTF3000US are substantially equivalent.