June 20, 2023

Xiamen Intretech Inc.
% Megan Callanan
Regulatory and Compliance Manager
Natural Cycles
510 5th Avenue 3rd Floor
New York, New York 10036

Re: K223522
Trade/Device Name: NC° Thermometer (Gen 3), Model Number: NCTG3
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 19, 2023
Received: May 19, 2023

Dear Megan Callanan:

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, 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)*
K223522

Device Name
NC° Thermometer (Gen3),
Model Number: NCTG3

Indications for Use *(Describe)*
The NC° Thermometer (Gen3) is used orally for the intermittent measurement and monitoring of human body temperature. The device can be used by adults and children over the age of 5 years old.

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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K223522

510(k) Summary: NC° Thermometer (Gen3)

Applicant:	Xiamen Intretech Inc. No.100 Dongfu West Road Haicang District, Xiamen Fujian, China Zip:361027
Applicant Contact:	Name: Sunny Sun Phone: 86-15750706715 Email: xmshj@intretech.com
Correspondent:	Name: Megan Callanan Phone: (216)744-4524 Email: Megan.callanan@naturalcycles.com
Date Prepared:	June 17, 2023
Trade Name:	NC° Thermometer (Gen3), Model Number: NCTG3
Common Name:	Clinical electronic thermometer
Proposed Class:	Class II
Classification Name:	Clinical electronic thermometer
Regulation Number:	21 CFR 880.2910
Product Code:	FLL
Predicate Device:	K173730 KSA-110 Clinical electronic thermometer from KINSA,INC , marketed as the Kinsa QuickCare Thermometer.
Device Description:	The purpose of this traditional 510(k) premarket notification is to introduce NC° Thermometer (Gen3). NC° Thermometer (Gen3) is a battery powered, thermistor- based Bluetooth Low Energy (BLE) and Near Field Communication (NFC) enabled adjusted mode digital thermometer that uses a predictive algorithm for the measurement and monitoring of human body temperature. Body temperature is measured orally with the NC° Thermometer. Temperature measurements are displayed on the thermometer and can also (optionally) be transmitted to the Natural Cycles application on the user's smartphone by women over the age of 18. The compatible application displays the thermometer temperature value. The

	thermometer is reusable for home use on adults and children ages 5 and above. The thermometer is made of biocompatible metals and resins. The thermometer consists of a Negative Temperature Coefficient (NTC) thermistor located in the probe tip to sense human body temperature, three input user facing buttons, an output buzzer for audio indications, a screen for user display, and back lights for illuminating the buttons.
Indications for Use:	The NC° Thermometer (Gen3) is used orally for the intermittent measurement and monitoring of human body temperature. The device can be used by adults and children over the age of 5 years old.

Summary of Technical Characteristics:

The technology of the NC° Thermometer (Gen3) is identical to the predicate device in terms of its principle of operation, thermistor, use of a prediction algorithm, and probe tip design. The industrial design is similar to the predicate except for the outer shell form.

Element of comparison	Subject Device NC° Thermometer (Gen3) K223522	Predicate Device Kinsa QuickCare Thermometer K173730	Verdict
Thermometer type	Predictive digital	Predictive digital	Same
Indications for Use	The NC° Thermometer (Gen3) is used orally for the intermittent measurement and monitoring of human body temperature. The device can be used by adults and children over the age of 5 years old.	The Kinsa QuickCare Thermometer is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm. The device is for the adult and pediatric population.	Similar[1]
Fundamental technology & Operating principle	Utilizes an NTC thermistor located in the probe tip to sense human body temperature when placed in the desired measuring site (mouth). The resulting change in resistance is sensed and monitored in order to through use of	Utilizes an NTC thermistor located in the probe tip to sense human body temperature when placed in the desired measuring site (mouth, underarm, and rectum). The resulting change in resistance is sensed and monitored in order to through	Similar[2]

	predictive algorithms estimate human body temperature.	use of predictive algorithms estimate human body temperature.	
Sensor	Thermistor based	Thermistor based	Same
Signal processing and display	Internal firmware and local screen display - Also able to transfer transmit data to an auxiliary device for secondary display	Internal firmware and local LCD display - Also able to transfer transmit data to an auxiliary device for secondary display	Same
Wireless Interface	Bluetooth Low Energy (BLE) and Near Field Communication (NFC)	Bluetooth Low Energy (BLE)	Different[1]
Compatible Application Name	Natural Cycles	Kinsa	Different[2]
Compatible Application Display of Thermometer Related Data	Temperature, timestamp	Temperature, timestamp, tips from our in-house clinician, share your illness timeline with another caregiver or your doctor	Different[3]
Power requirements	Battery powered CR2032 (3V)	Battery powered (CR2032 (3V)	Same
Patient Contacting Materials	SUS316L, ABS, PMMA, ABS+SMMA	SU304 Stainless Steel, ABS, PMMA	Similar[3]
Scale	°F / °C	°F / °C	Same
Measurement locations	Oral	Oral, Axillary and Rectal	Different[4]
Measurement Range	32 to 42 °C (89.6 to 107.6 °F)	32 to 42.8 °C (89.6 to 109.2 °F)	Different[5]
Number of measurements that can be saved and viewed on thermometer	10	N/A- No history button on thermometer	Different[6]
Thermometer Buttons	Power button, setting button, history button	Power button	Different[7]
Operating Environment	15 to 40°C ≤ 95% relative humidity, non-condensing	15 to 35 °C 15 to 85% Relative humidity, non-condensing	Different[8]

Storage Environment	-25 to 50 °C ≤ 95% relative humidity 70kPa to 106kPa	-25 to 70 °C Up to 90% relative humidity, non-condensing, up to 50 hPa	Different[9]
Accuracy	±0.2℃/0.3°F (Temperature less than 37℃/98.0°F) ±0.1℃/0.2°F (Temperature 37.0℃ to 39.0℃/98.0°F to 102.0°F) ±0.2℃/0.3°F (Temperature greater than 39.0℃/102.0°F)	± 0.2°C within measurement range of 32 to 42.8°C (89.6 to 109.2°F)	Different[10]
Response Time	40 seconds nominally	8 seconds nominally	Different[11]
Resolution of Display	0.01 °C / 0.01°F	0.1 °C / 0.1°F	Different[12]
Performance	Meets ISO 80601-2-56:2017	Meets ISO 80601-2-56	Same
Biocompatibility	Meets ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Meets ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010	Same
Electrical Safety	Meets AAMI/ANSI ES 60601-1:2005+A2:2020	Meets AAMI/ANSI ES 60601-1:2005+A1:2012	Same
Electromagnetic Disturbances	Meets IEC 60601-1-2:2014	Meets IEC 60601-1-2:2014	Same

Discussion of Similar Elements of Comparison:

1. Similar indications for use: The subject device can only be used for adults and children over the age of 5. The predicate device indications for use do not specify a pediatric age limit. As the subject device is intended for oral use only, the intended user was limited to children over the age of 5 years old and adults. Performance testing demonstrates that the subject device meets ISO 80601-2-56 and the different pediatric age limit does not raise any new safety and effectiveness questions.
2. Similar fundamental technology and operating principle: Similar hardware is used in both devices. Performance testing demonstrates that the subject device meets ISO 80601-2-56 and ASTM E1112. The differences in fundamental technology and operating principle do not raise any new safety and effectiveness questions.
3. Similar patient contacting materials: The thermometer materials are similar except for the probe tip and buttons. The subject device probe tip uses an equivalent biocompatible stainless steel and the subject device buttons include an additional thermoplastic, SMMA. All skin contacting materials in the subject device have been tested successfully for biocompatibility: cytotoxicity in accordance with AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological Evaluation of

Medical Devices Part 5: Tests for In Vitro Cytotoxicity, as well as irritation and sensitization in accordance with AAMI/ANSI/ISO 10993-10:2010/(R)2014, Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization. The materials used in the subject device do not raise any new questions of safety and effectiveness.

Discussion of Different Elements of Comparison:

1. Different wireless interface: The subject device has NFC interface in addition to BLE, while the predicate device has BLE. NFC is a widely used technology and the subject device has passed electrical safety and electromagnetic compatibility testing in accordance with the FDA recognized consensus standards: AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012, IEC 60601-1-2:2014, IEC60601-1-11 Edition 2.1 2020-07, FCC Part 15 Subpart C § 15.247, and FCC Part 15 Subpart C § 15.225. Additionally, performance data consisting of software verification, cybersecurity analysis, wireless coexistence testing, usability testing demonstrate the safe and effective use of this feature. The essential performance of the subject device is not compromised as the primary display of the temperature readings on the thermometer's local screen is independent of the wireless transmission. The addition of the NFC wireless interface does not raise different questions of safety and effectiveness.
2. Different compatible application name: Subject and predicate thermometers are compatible with different applications. Both applications are downloaded onto smartphones and allow users to see temperature and timestamp. The essential performance of the subject device is not compromised as the primary display of the temperature readings on the thermometer's local screen is independent of the wireless transmission. The subject device has passed electrical safety and electromagnetic compatibility testing in accordance with the FDA recognized consensus standards: AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012, IEC 60601-1-2:2014, IEC60601-1-11 Edition 2.1 2020-07, FCC Part 15 Subpart C § 15.247, and FCC Part 15 Subpart C § 15.225. Additionally, performance data consisting of software verification, cybersecurity analysis, wireless coexistence testing, usability testing demonstrate the safe and effective use of the subject device and compatible application.
3. Different compatible application display of temperature related data: The predicate thermometer's compatible app provides more information regarding illness but both apps function equivalently when receiving temperature and timestamp data and displaying it on the phone. The predicate thermometer's compatible application has additional features related to illness such as tips from clinician and illness timeline but these features do not impact the safe and effective use of the thermometer. The subject thermometer compatible app is a medical device while the predicate is not but this does not impact the app with respect to the thermometer. The subject device has passed electrical safety and electromagnetic compatibility testing in accordance with the FDA recognized

consensus standards: AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012, IEC 60601-1-2:2014, IEC60601-1-11 Edition 2.1 2020-07, FCC Part 15 Subpart C § 15.247, and FCC Part 15 Subpart C § 15.225. Additionally, performance data consisting of software verification, cybersecurity analysis, wireless coexistence testing, usability testing demonstrate the safe and effective use of the subject device and compatible application.

4. Different measurement locations: The subject device is used for oral measurement only. The route of temperature measurement for the subject device is a subset of the routes available using the predicate device. Both the subject and predicate devices are used for oral measurements. The subject device meets the requirements of ISO 80601-2-56 and ASTM E1112 for oral use and the limitation on measuring routes does not raise any different questions of safety and effectiveness.
5. Different measurement range: The subject device has a lower upper limit of measurement range than the predicate device. The ISO 80601-2-56 performance testing of the subject device demonstrated that the difference does not raise any new questions of safety and effectiveness.
6. Different number of measurements that can be saved and viewed on thermometer: There is no history button on the predicate device and thus no measurements can be saved and viewed on the thermometer. The subject device has a history button, but this does not impact the essential performance of the subject device. Software verification, design verification, and usability testing demonstrates that the history button and display of previous measurements on the thermometer does not raise any new questions of safety and effectiveness.
7. Different thermometer buttons: Compared to the predicate device, there are two more buttons (history button and settings button) on the subject device. The essential performance of the subject device is not compromised as temperature measurement and display of temperature readings is independent of History and Settings buttons. Performance data consisting of software verification, design verification, and usability testing demonstrates the safe and effective use of all buttons. It does not raise new questions of safety and effectiveness.
8. Different operating environment: The subject device has larger operating range and higher humidity requirements than the predicate device. The operating environment requirements on the subject device and the predicate device both meet the IEC 60601-1-11 and ISO80601-2-56 standards and performance testing conducted according to these standards demonstrates that the difference in operating environment does not raise any new questions of safety and effectiveness.
9. Different storage environment: The subject device has a smaller storage range and higher humidity limitation. The storage environment requirements on the subject device and the predicate device both meet the IEC 60601-1-11 and ISO80601-2-56 standards and performance testing conducted according to these standards demonstrates that the difference in storage environment does not raise any new questions of safety and effectiveness.

10. Different accuracy: The subject device meets ISO80601-2-56 and ASTM E1112 requirements, while the predicate device meets ISO80601-2-56. The subject device has higher accuracy than the predicate device from 37 to 39°C because ASTM E1112 has stricter accuracy requirements. Performance testing was conducted on the subject device according to ASTM E1112 and ISO80601-2-56. The difference does not raise any new performance or safety concerns.
11. Different response time: The subject device has longer measurement time than the predicate device, but usability testing showed the measuring time is well within user expectations and far below the 3 minutes that would be required without a predictive algorithm. This specification has been validated by the testing per ISO 80601-2-56 and ASTM E1112. The difference does not raise any new questions of safety and effectiveness.
12. Different resolution of display: The subject device has a higher resolution of display than the predicate device. Performance testing demonstrated that the subject device is in compliance with both ISO 80601-2-56 and ASTM E1112 requirements. The difference in resolution of display does not raise any new questions of safety and effectiveness.

Testing to Demonstrate Substantial Equivalence:

Non-clinical Testing

Non-clinical performance reports were provided to document verification and validation activities intended to demonstrate substantial equivalence of the subject device to the predicate device:

1. Design Verification results confirmed the device meets the product requirements set by and the performance standard requirements of ISO 80601-2-56:2017, Medical Electrical Equipment – Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement and ASTM E 1112-00 (2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.
2. Software Verification and Validation results confirmed the firmware and software units meet the software requirements specifications and the system performs as intended. Software documentation is provided in accordance with the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).
3. Cybersecurity hazards and risks associated with the thermometer have been evaluated. Cybersecurity information is provided in accordance with the FDA Guidance "Content of Premarket Submission for Management of Cybersecurity in Medical Devices"
4. All skin contacting materials have been tested successfully for biocompatibility: cytotoxicity in accordance with AAMI/ANSI/ISO 10993-5:2009 /(R)2014, Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity, as well as irritation and sensitization in accordance with AAMI/ANSI/ISO 10993-

10:2010/(R)2014, Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization.

5. Electrical and Mechanical Safety as well as essential performance was confirmed through compliance testing to AAMI/ANSI ES 60601-1:2005/(R)2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-11:2015, Medical Electrical Equipment Part 1-11: Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
6. Electromagnetic Compatibility was confirmed through compliance testing to IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: Electromagnetic Disturbances – Requirements and Tests.
7. FCC compliance was confirmed through testing to FCC Part 15 Subpart C §15.247/ RSS 247.
8. Interoperability testing was completed to ensure that the thermometer is able to communicate with the Natural Cycles application as intended.

Clinical Testing

To support the performance of the NC° Thermometer (Gen3), a clinical validation study was performed. The study evaluated the clinical performance of the NC° Thermometer (Gen3) to a reference clinical thermometer in accordance with ISO 80601-2-56. Clinical validation study reports were provided with this submission. The pivotal clinical study included 105 participants, 32 (30%) were febrile. All participants were over the age of 5 years old. 64 participants (61%) were female and 41 participants (39%) were male. Based on the clinical performance as documented in the pivotal clinical study, the NC° Thermometers (Gen3) was found to meet the ISO 80601-2-56 requirements of clinical accuracy for an adjusted thermometer.

Conclusion:

Based on the design features, the use of established well known materials, feature comparisons, and indications for use, the NC° Thermometer (Gen3) has demonstrated substantial equivalence to the identified predicate device.