July 23, 2021

Shenzhen BSX Technology Electronics Co., Ltd.
Lijuan Du
RA Engineer
Rm301.3F 8th Building, LiHao Industrial Area,
No.78 AiNan Road
Shenzhen, Guangdong 518116
China

Re: K202296
Trade/Device Name: Infrared Forehead Thermometer, Model BSX976
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 21, 2021
Received: June 21, 2021

Dear Lijuan Du:

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,

Payal Patel
Acting 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)*
K202296

Device Name
Infrared Forehead Thermometer(Model:BSX976)

Indications for Use *(Describe)*
The Infrared forehead thermometer is a non-contact infrared thermometer (model BSX976) intended for the intermittent measurement of temperature from forehead at a distance of 1~3cm for people older than 2 years. The device is reusable for home use and clinical use and the safety of the device has not been established for use in neonates/infants.

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 – K202296

1. Submitter:

Table 1 Submitter (Owner) and Contact Information

Company / Institution Name			
Shenzhen BSX Technology Electronics Co., Ltd.			
Phone Number (including area code)	**FAX Number (including area code)**		
+86 0755 28719103	+86 0755 28882567		
Street Address			
Rm301.3F＆4F 8th Building, LiHao Industrial Area, No.78 AiNan Road Longgang			
City	**State/Province**	**ZIP/Postal Code**	**Country**
Shenzhen	Guangdong	518116	China
Contact Name			
Yolanda L			
Contact Title	**Contact E-mail Address**		
Consultant	Yolanda.bleu@foxmail.com		

Date Prepared: 2021-05-08
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

2. Device Information:

Type of 510(k) submission: Traditional
Trade Name: Infrared Forehead Thermometer
Common Name: Clinical Electronic Thermometer
Model: BSX976
Classification name: thermometer, electronic, clinical
Review Panel: General Hospital
Product Code: FLL
Device Class: II
Regulation Number: 880.2910

3. Predicate device:

Sponsor: KAZ USA, Inc., A Helen of Troy Company
Product Model: Forehead NTF3000 Thermometer
Trade Name: Braun No Touch + Forehead NTF3000 Thermometer
Classification name: thermometer, electronic, clinical
Device Class: II
Regulation Number: 880.2910
510(K) Number: K163516

4. Indications for Use

The Infrared forehead thermometer is a non-contact infrared thermometer (model BSX976) intended for the intermittent measurement of temperature from forehead at a

distance of 1~3cm for people older than 2 years. The device is reusable for home use and clinical use and the safety of the device has not been established for use in neonates/infants

5. Basic principle

Any object in which temperature is higher than absolute zero degree will transmit some infrared radiation energy according to its own temperature. The radiation energy and its distribution per wavelength are closely associated with its surface temperature. Based on the principle, it is possible to measure the forehead temperature and then adjust the offset between forehead temperature and actual body temperature, which will result in the correct display of body temperature.

6. Device Description

BSX976 measures the body temperature through receiving the infrared energy radiation from the surface of objects. It is with forehead temperature mode, directly show on the LCD screen.

- The device is widely used for home healthcare, medical institutes, and many other occasions.
- The product is mainly composed with infrared temperature sensors, signal receiving processor, buttons, buzzer, LCD display, battery, etc.
- It focuses the infrared from the human's forehead by the Fresnel lens.

7. Performance Data

Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the BSX976 Infrared Forehead thermometer device, consisting of all the modules and accessories in the system. The system complies with the ANSI/AAMI ES60601-1 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the 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* standard for EMC.

Bench Testing

Bench testing was conducted on the BSX976 Infrared Forehead thermometer device, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11 *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*, ISO 80601-2-5 *Medical electrical equipment — Part 2-56: Particular requirements for basic*

safety and essential performance of clinical thermometers for body temperature measurement and ASTM E 1965-98 Standard Specification For Infrared Thermometers For Intermittent Determination Of Patient Temperature standards for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:
Clinical testing is conducted per ISO 80601-2-56 Clause 201.102, and 150 subjects were involved in the testing, 32 of which were febrile.

Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a performance that is similar to the predicate device.

8. Comparison to predicate device

Table 2 Similarity and difference analysis between Subject Device and Predicate Device

ITEM	Proposed Device	Predicate Device K163516	Comparison Result
Manufacturer	Shenzhen BSX Technology Electronics Co., Ltd.	KAZ USA, Inc., A Helen of Troy Company	---
Product name and Model	Infrared Forehead Thermometer BSX976	Braun No Touch + Forehead NTF3000 Thermometer	---
Indications for Use	The Infrared Forehead Thermometer is a non-contact infrared thermometer (model BSX976) intended for the intermittent measurement of temperature from forehead at a distance of 1~3cm for people older than 2 years. The device is reusable for home use and clinical use and the safety of the device has not been established for use in neonates/infants.	The Braun No Touch + Forehead NTF3000 Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.	Different [1]
Measuring Site	Forehead	Forehead	Same
Measuring mode	Adjusted	Adjusted	Same
Detection method	Temperature is detected by thermistor and calculated.	Temperature is detected by thermistor and calculated.	Same
Design principle	Based on Infrared Sensor technology	Based on Infrared Sensor technology	Same
Measurement Range	32.0℃～43.0℃	34.4℃～42.2℃	Different [2]
Measurement Distance	1~3 cm	0~5 cm	
Measurement Accuracy	32 ℃ to 43 ℃: ±0.3 ℃	35 ℃ to 42 ℃: ±0.2 ℃ 31 ℃ to 35 ℃: ±0.3 ℃ Above 42℃: ±0.3 ℃	
Resolution of Display	0.1°C/°F	0.1°C/°F	Same
Signal output and display	LCD, Buzzer	LCD, Buzzer	Same
Lens Filter	NO	NO	Same
Response time	within 3 seconds	within 2 seconds	Different [3]
signal processing	A/D signal processing mode	A/D signal processing mode	Same
sensor model	STP9CF55H	----	---
backlight feature	Green:34.0～37.5℃, Yellow:37.6～38.0℃, Redr:38.1～42.9 ℃	Green, > 35.7° – 37.4 °C Yellow, > 37.4° – 38.5 °C Red, > 38.5° – 42.2 °C	Different[3]

Integrated circuitry model	MCU: HME055	MCU: Weltrend WT5075F	Different [4]
Operating Environment	15℃ to 40℃ (59.0℉to 104.0℉) ,20%~95%RH,70kPa to 106kPa	15°C ~ 40°C ≤85% moisture condensation	Different [5]
Storage Environment	Temperature: -20 °C to 55 °C (-4 °F – 131 °F) Humidity: 15–95% non-condensing	-25°C~60°C ≤95% moisture condensation	
Power supply	2* 1.5 V AAA Batteries	Two (2) AA batteries	Different[6]
Applicable standards	ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO80601-2-56	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO80601-2-56	Same
Memory Data Limit	20 sets	No	Different[7]
Product configuration	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	Same
Temperature unit and conversion	Dual temperature units "°C" and "°F" optional, and the two units can convert by the conversion key automatically	Dual temperature units "°C" and "°F" optional and the two units can convert by the conversion key automatically	Same
physical dimensions (mmc)	190×78×50mm	200x60x134mm	Different [8]
Weight	82g (with batteries), 64g (w/o batteries)	99.5 g (with batteries), 77.1 g (w/o batteries)	

Justification for the differences:

1) Different Indications for Use

Both the candidate device and the predicate are used to measure the forehead temperature with non-contact mode, the difference is just different language description, no substantial difference, therefore, no safety or effectiveness questions will be raised.

2) Different Measurement Range, Distance and Accuracy

The subject BSX976 shows minor different measurement range, measurement distance and accuracy from those of the predicate, but the verification and validation data demonstrated the compliance of requirements established in the Standard ASTM E1965-98 and ISO 80601-2-56. And the current measurement range can meet the clinical practice for operation. Hence, the minor difference will not cause any safety and effectiveness problems.

3) Different Response Time & Backlight Feature

The subject device shows different response time to predicate device, but the device passed ISO 80601-2-56 particular requirement test which would not raise safety and effectiveness concerns.

The subject device shows different backlight feature in different measurement range to predicate device, but the subject device passed IEC 60601-1 and ISO 80601-2-56 safety and particular requirement test which would not raise safety and effectiveness problems

4) Different Integrated Circuitry Model

The subject device pass IEC 60601-1 and ISO 80601-2-56 test which can demonstrate the safety and effectiveness of the device.

5)Different Operation & Storage Environment

Minor Operation & Storage Environment difference has also been verified during the design process, and the international standards IEC 60601-1 and IEC 60601-1-11, do not raise concerns related to the device safety and effectiveness.

6)Different Power Supply

Minor different batteries would not raise concerns related to the device safety and effectiveness for the pass of IEC 60601-1 power safety test.

7) Different Memory Function

The subject BSX976 can store memorize 20 measurements automatically while the predicate does not have the function, which is not the significant difference which will cause the safety and effectiveness, and this functionality has been well verified and can be found in the software submission documentation.

8) Different Dimension & Weight

The weight of BSX976 is less and dimension is smaller than the predicate device, but the physical characteristics difference will not raise any safety and effectiveness problem because it has been verified during the design and development.

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, including the appearance, measurement range, measurement distance and accuracy, power supply, and operating environment which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the performance of the BSX976 Infrared Forehead Thermometer.

9. Conclusion

Based on the above considerations table, the Proposed Device, the BSX976 Infrared thermometer is substantially equivalent to the predicate device Braun No Touch + Forehead NTF3000 Thermometer (K163516).