December 14, 2020

Shenzhen BSX Technology Electronics Co., Ltd.
Fang Kai
General Manager
Rm301.3F 8th Building, LiHao Industrial Area,
No.78 AiNan Road, Longgang
Shenzhen, Guangdong 518116
China

Re: K202324
Trade/Device Name: Fingertip Pulse Oximeter, Models BSX221, BSX223, BSX261, BSX263, BSX281, BSX283, BSX231, BSX233, BSX251, BSX253
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 20, 2020
Received: November 27, 2020

Dear Fang Kai:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202324

Device Name
Fingertip Pulse Oximeter, Models BSX221, BSX223, BSX261, BSX263, BSX281, BSX283, BSX231, BSX233, BSX251, BSX253

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults or children over three years old in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

## Prepared in accordance with the requirements of 21 CFR Part 807.92
## K202324

| | |
|---|---|
| **1. Submitter:** | Shenzhen BSX Technology Electronics Co., Ltd.<br>Rm301.3F 8th Building, LiHao Industrial Area, No.78 AiNan Road, Longgang District, Shenzhen, 518116, P.R. China<br>TEL: +86 755 28719103 |
| **Contact Person:** | Fang Kai |
| **Prepare date:** | 2020-09-12 |
| **2. Device name and classification** | **Device Name:** Fingertip Pulse Oximeter<br>**Models:** BSX221, BSX223, BSX261, BSX263, BSX281, BSX283, BSX231, BSX233, BSX251, BSX253<br>**Classification Name:** 21 CFR 870.2700 Oximeter<br>**Product code:** DQA<br>**Regulatory Class:** Class II<br>**Class III Summary and Certification:** Not applicable<br>**IVD Classification:** Not applicable |
| **3. Reason for Submission** | New Application. No prior submission associated with the current submission. |
| **4. Predicate Device(s)** | Shenzhen Yimi Life Technology Co., Ltd., YM101/YM201/YM301 Pulse Oximeter / K191430 |
| **5. Device Description** | The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation ($SpO_2$).<br>The subject device is a reusable device, and need to reprocess as suggested in the user manual after each use. And the device is intended to be used on the finger, and powered by 2*1.5V AAA battery. The differences between different models only includes the color of the non-patient contacting shell part and the size. And the color display screen of BSX221/BSX223/BSX261/BSX263/BSX281/BSX283 is OLED, while that of BSX231/BSX233/BSX251/BSX253 is TFT. |
| **6. Indications for Use** | The Fingertip Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults or children over three years old in |

healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

## 7. Predicate Device Comparison

Please refer to following table to find differences between the subject device and predicate device.

Table 1 Comparison between the predicate and the subject devices

| ITEM | Predicate Device YM 101/YM201/YM301 Pulse Oximeter K191430 | Proposed Device BSX221, BSX223, BSX261, BSX263, BSX281, BSX283, BSX231, BSX233, BSX251, BSX253 | Comparison Result |
|---|---|---|---|
| Manufacture | Shenzhen Yimi Life Technology Co., Ltd. | Shenzhen BSX Technology Electronics Co., Ltd. | --- |
| Indications for Use | The pulse oximeter is intended for measure oxygen saturation and pulse rate of adult patients in healthcare environments. | The Fingertip Pulse Oximeter is intended for measure oxygen saturation and pulse rate of adults or children over three years old. | Different |
| Intended patient population | Adult | Adult or children over three years old | |
| Contraindications | Not intended to be used under motion or low perfusion scenarios. | Not intended to be used under motion or low perfusion scenarios. | Same |
| **Operational Specifications** | | | |
| Intended application site | Finger | Finger | Same |
| Measurement Principles | 2-wavelength Relative Optical Absorption | 2-wavelength Relative Optical Absorption | Same |
| Signal Detection Method | Photodetector | Photodetector | Same |
| Display content | SpO2%, PR, battery indicator, Pulse rate bar graph，pulse waveform | SpO2%, PR, battery indicator, Pulse rate bar graph，pulse waveform | Same |
| $SpO_2$ Range | 0%~100% | 35%~100% | Different |
| $SpO_2$ Accuracy | 70~100%: ±2% 0% to 69%: unspecified | 70% ~79%:±3%; 80%~100%:±2%; 0% to 69%: unspecified | |
| $SpO_2$ Resolution | 1% | 1% | Same |
| Pulse Rate Range | 25 bpm ~ 250 bpm | 30 bpm ~ 250 bpm | Different |
| Pulse Rate Accuracy | ±2 bpm | ±3 bpm | |
| Pulse Rate Resolution | 1 bpm | 1 bpm | Same |
| Data Memory | Not available | 20 sets | Different |
| Shipped Sterile | No | No | Same |
| Power suppler | 2*1.5V AAA alkaline battery | 2*1.5V AAA alkaline battery | Same |

| | | | |
|---|---|---|---|
| Safety classification | Class IIa, Internally powered, Type BF applied part, IP22 | Class IIa, Internally powered, Type BF applied part, IP22 | Same |
| Storage and Transport Environment | Temperature: -20℃ to 60℃<br>Atmospheric Pressure: 50 kPa to l07.4 kPa<br>Relative Humidity: 10%-95% (no condensation) | Temperature: -20℃to 55℃<br>Atmospheric Pressure: 70 kPa to 106 kPa<br>Relative Humidity: ＜93% (no condensation) | Different |
| Operating Environment | Temperature: 15℃to 40℃<br>Atmospheric Pressure: 70 kPa to 106 kPa<br>Relative Humidity: 15%-95% (no condensation) | Temperature: 10℃to 40℃<br>Atmospheric Pressure: 70 kPa to 106 kPa<br>Relative Humidity: 30%-75% (no condensation) | |
| **Compliance Standards** | | | |
| Bio-compatibility | ISO 10993-1<br>ISO 109903-5<br>ISO 10993-10 | ISO 10993-1<br>ISO 109903-5<br>ISO 10993-10 | Same |
| Electrical Safety | IEC 60601-1<br>IEC 60601-1-11 | AAMI/ANSI EC 60601-1<br>IEC 60601-1-11 | |
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | |
| Performance | ISO 80601-2-61 | ISO 80601-2-61 | |

As seen in the comparison tables, the subject and predicate devices have same design principle, similar design features and performance specifications. The different technological characteristics between the subject and predicate devices will not raise different questions of safety or effectiveness.

## 8. Performance Testing

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

**Non-Clinical Testing:**

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

### Biocompatibility testing

The biocompatibility evaluation for the Fingertip Pulse Oximeter was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

### Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the *ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)* for safety and the IEC 60601-1-2: 2007 *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 and the results show that the subject device complies with the ISO 80601-2-61: 2017 *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment* standard. And Pulse Rate Accuracy meets the requirements defined in ISO 80601-2-61, Clause 201.12.1.104.

### Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the* Content *of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern.

### Cleaning Validation

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17,2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the manual.

### Clinical data:

Clinical testing is conducted per *Annex EE Guideline for evaluating and documenting $SpO_2$ ACCURACY in human subjects* of *ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*

## 9. Conclusion

Verification and validation testing was conducted on the subject device Fingertip Pulse Oximeter and all testing passed pre-specified criteria. The subject device and the predicate device has the same intended use, and the difference in technological features do not raise different questions of safety and effectiveness.This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device.