



January 7, 2026

Shenzhen Best Electronics Co., Ltd.
% Lucy Yan
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, GuangDong 518100
China

Re: K253109

Trade/Device Name: Reusable SPO2 Sensor (BSA307-47; BSA109-50; BSA109-31O)

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: December 8, 2025

Received: December 8, 2025

Dear Lucy Yan:

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 (the 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 available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn

Assistant Director

DHT1C: Division of Anesthesia,

Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253109

?

Please provide the device trade name(s).

?

Reusable SPO2 Sensor (BSA307-47; BSA109-50; BSA109-310)

Please provide your Indications for Use below.

?

The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) patients.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

SECTION 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted as Required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

| | |
|--|--|
| Date of Summary prepared Manufacturer information | Nov. 1, 2025 Company: Shenzhen Best Electronics Co., Ltd. Company address: 605 No. 59 Building, The Second Industrial Zone, Tianliao Community, Yutang Street Guangming District, Shenzhen, China. Contact person: Martin Wong Phone: +8613923770214 Fax: +86-755-27192975 E-mail: 307294149@qq.com |
| Submission Correspondent  | Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China Contact person: Ms. Lucy Yan E-Mail: lucy@cefda.com |
| Establishment registration number | |

5.2 Device Information

| | |
|-----------------------------------|----------------------------------|
| Type of 510(k) submission: | Traditional |
| Trade Name: | Reusable SpO ₂ Sensor |
| Model: | BSA307-47; BSA109-50; BSA109-310 |
| Classification name: | Pulse Oximeter Sensor |
| Review Panel: | Cardiovascular |

| | |
|---------------------------|----------|
| Product Code: | DQA |
| Device Class: | II |
| Regulation Number: | 870.2700 |

5.3 Predicate Device Information

| | |
|-----------------------|---|
| Sponsor: | Shenzhen Caremed Medical Technology Co., Ltd. |
| Device: | Caremed Reusable & Disposable SpO2 Sensors |
| 510(K) Number: | K153184 |

5.4 Device Description

The Reusable SpO2 Sensors are comprised of a connector and a cable which terminates into sensor housing.

The sensors contain two specific wavelength LEDs and a photo detector assembled into the sensor housing which separate by one housing half and the other half. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter.

One types of sensor housings are described in this submission:
Reusable finger clip sensor with rigid halves and silicone pads

Reusable finger clip sensor which is multi-use.

The Reusable SpO2 Sensors mainly are used in hospital, health center, etc. which is not intended for out-of-hospital transport and for home use.

Each sensor has been designed for compatibility with the specific monitor (Nellcor, Nihon, Ohmeda), please refer to the following table:

| Reusable SpO2 sensor model | Compatible device |
|----------------------------|--------------------------------|
| BSA307-47 | Nellcor N-595 (K012891) |
| BSA109-50 | Nihon Kohden OPV1500 (K032749) |
| BSA109-310 | Datex Ohmeda (K062576) |

The Reusable SpO2 Sensors are typically screen for or diagnose a disease or condition with a general indication for non-invasive measurement of blood oxygen saturation.

The Reusable SpO2 Sensors are not intended to be marketed with multiple components, accessories.

The application site is the finger for the Reusable SpO2 Sensors which are not non-sterile.

The device is multi-use.

5.5 Intended Use/ Indications for Use

The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) patients.

These products are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.

5.6 Technological characteristics of the subject device compared to the predicate device

Predicate Device Information:

510(K) No.: K153184
 Common name: Oximeter
 Classification name: Oximeter
 Production regulation: 21 CFR § 870.2700
 Product code: DQA
 Panel: Cardiovascular

Comparison to predicate device:

| Comparison item | Subject Device | Predicate Device K153184 | Remarks |
|--------------------------|-------------------------------------|---|---------|
| Product name | Reusable SPO2 sensor | Caremed Reusable & Disposable SpO2 Sensors | |
| Manufacturer | Shenzhen Best Electronics Co., Ltd. | Shenzhen Caremed Medical Technology Co., Ltd. | / |
| Product Code | DQA | DQA | same |
| Regulation Number | 870.2700 | 870.2700 | same |
| Classification | II | II | same |

| | | | |
|--|--|--|------------------|
| Intended use& Indications for Use | The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) patients. Prescription device. | Caremed Reusable & Disposable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg and pediatric patients weighing 10 -50 kg. Prescription device. | SE |
| Measurement Method | 2-wavelength Relative Optical Absorption | 2-wavelength Relative Optical Absorption | same |
| Light Emitting | BSA307-47: Red: 660nm±10nm Infrared: 905nm±10nm; BSA109-50, BSA109-31O: Red: 663±3nm Infrared Red 940±10nm | Red:660-666nm, Ired:880-950nm | SE |
| Signal Detection Method | Photodetector | Photodetector | same |
| SPO2 Accuracy | ±3% (70-100%) | ±3% (70-100%) | same |
| Pulse Rate Accuracy | ±3(30-250bpm) | ±3(30-250bpm) | same |
| Applied population | BSA307-47, BSA109-50, BSA109-31O: Adult(≥40Kg) | C403-01 & C403S-15: Adult(≥40Kg) N543-01: Adult(≥40Kg) & Pediatric(10-50Kg) | SE |
| Measurement part | Fingers | Fingers or toes | SE |
| Compatible monitor | Nellcor N-595, Nihon kohden, or Datex Ohmeda | Nellcor Non oximax (N395) & Masimo set | Different Note 1 |
| Sterile | No | No | same |
| Usage | Reusable | Reusable & disposable | SE |

| | | | |
|--|--|--|------------------|
| Material | ABS, TPU, Silicone | ABS, PVC, TPU, Silicone, sponge | Different Note 2 |
| Cable Length | 2.9m or 1m | 1.1m | Different Note 3 |
| Proximal connector Design | DB9 9pin | DB9 9pin&1269 LNOP DC | SE |
| Distal connector Design | BSA307-47, BSA109-50, BSA109-310: Finger clip | finger clip and sponge adhesive | Different Note 4 |
| Biocompatibility | Cytotoxicity Irritation Sensitization | Cytotoxicity Irritation Sensitization | same |
| Electrical Performance and Safety | IEC60601-1, IEC60601-1-2, ISO80601-2-61, ISO10993-5/10/23 | IEC60601-1, IEC60601-1-2, ISO80601-2-61, ISO10993- 5/10 | same |

Substantial Equivalence Discussion

Note 1: Compatible monitors

The Compatible monitors of the subject device are different from the predicate device. The design of the subject device is used with the Compatible monitors. The safety test and the clinical test was conducted and the reusable SPO2 sensors with Compatible monitors passed the IEC 60601-1 and ISO 60601-2-61. Therefore, the difference between the subject and predicate devices do not raise safety and effectiveness issues.

Note 2: Material

The subject reusable spo2 sensors have the same material of patient end, and the cable connecting with skin material is different, the subject device's is TPU, but the predicate device has another material PVC. The reusable sensors passed the test of ISO10993-5/10/23 requirements. so, this difference also does not raise different questions of safety and effectiveness.

Note 3: Cable Length

The Cable Length of the subject device are different from the predicate device. The safety test and the clinical test was conducted. The reusable SPO2 sensors with Compatible monitors passed the IEC 60601-1 and ISO 60601-2-61. Therefore, the difference between the subject and predicate devices do not raise safety and effectiveness issues.

Note 4: Distal connector Design

The Compatible monitors of the subject device are different from the predicate device. The Distal connector design of the subject device is used with the Compatible monitors which is DB9 9pin. The safety test and the clinical test was conducted. The reusable SPO2 sensors with Compatible monitors passed the IEC 60601-1 and ISO 60601-2-61. Therefore, the difference between the subject and predicate devices do not raise safety and effectiveness issues.

5.7 Brief discussion of the nonclinical tests

Reusable SpO2 Sensor conforms to the following standards:

IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012+A2:2021 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

IEC 60601-1-2: 2014+A1:2021 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

IEC TR 60601-4-2:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

ISO 80601-2-61:2017 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment

IEC 62471:2006 Photobiological safety of lamps and lamp systems

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization

ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for

irritation

5.8 Brief discussion of clinical tests

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Reusable SPO2 Sensors versus arterial oxygen saturation (SaO₂) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

The Reusable SpO₂ Sensor was accurate and safe which satisfied the requirements of FDA guidance and ISO 80601-2-61:2017 in the range of 70%-100%SaO₂.

5.9 Other information (such as required by FDA guidance/Test)

Animal performance testing is not required and was not performed to demonstrate safety and effectiveness of the Reusable SpO₂ Sensor.

5.10 Conclusions

Based on the above information, we conclude the subject device, Reusable SpO₂ Sensor, is substantially equivalent to the predicate device(K153184).