October 16, 2022

Shenzhen IMDK Medical Technology CO., Ltd.
℅ Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K221979
Trade/Device Name: Pulse Oximeter (Model C101A2, C101B1, C101A3)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 16, 2022
Received: September 16, 2022

Dear Boyle Wang:

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,

James J. Lee, Ph.D.
Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221979

Device Name
Pulse Oximeter(Model:C101A2,C101B1,C101A3)

Indications for Use *(Describe)*
Fingertip Pulse Oximeter (Model:C101A2,C101B1,C101A3) is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.

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

K221979

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Shenzhen IMDK Medical Technology Co., Ltd.
Address: C Zone, 10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, Shenzhen, Guangdong, P.R. China
Tel: 86-755-27155684
Contact: Yuan Xia
Registration Number: 3015007456

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Sep.27,2022

2.0 Device Information

Trade name: Pulse Oximeter
Common name: Pulse Oximeter
Classification name: Oximeter
Model(s): C101A2, C101B1, C101A3
Production code: DQA
Regulation number: 21 CFR 870.2700
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Shenzhen IMDK Medical Technology Co., Ltd.
Trade name: Pulse Oximeter, Model: C101H1

510(k) number: K173123

4.0 Indication for Use Statement

Fingertip Pulse Oximeter (Model: C101A2, C101B1, C101A3) is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.

5.0 Device Description

SpO2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO2 measuring unit. The light-electronic transducer in finger sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The PLETH curve and numeral value of SpO2 will be obtained. The pulse oximeter, model C101A2, C101B1, C101A3 is designed for spot checking of the pulse oxygen saturation and pulse rate for adults in a clinic environment. This medical device can be reused. Not for continuously monitoring.
The device is not for life-supporting or life-sustaining, not for implant.
The device is not provided sterile and is NOT a reprocessed single-use device.
The device is a spot-check pulse oximeter and does not include alarms.
The device does not support the measurement in the condition of low perfusion.
The device is not intended for life-supporting or life-sustaining.
The device is reusable and does not need sterilization.

6.0 Technological Characteristics

Principle of Operation
There is no change in the principle of operation as part of this submission from the previous clearance under K173123. The module still utilizes the same principles of operation for pulse oximetry governed by the following principles:
1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect
There is no change to the Mechanism of Action of the Pulse Oximeter (Model: C101A2, C101B1, C101A3) from the previous clearance K173123- Pulse Oximeter (Model: C101H1):
A mathematic formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and

Oxyhemoglobin (Hbo2) in red and near-infrared zones. Operation principle of the instrument: Photoeletric Oxyhemoglobin Inspection Technology adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeters display through process in electronic circuits and microprocessor.

7.0 Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device

The subject device, Pulse Oximeter (Model: C101A2, C101B1, C101A3) and the predicate device Pulse Oximeter (Model: C101H1), have the following key similarities:

- Both devices have the same intended use
- Both devices are indicated for the same patient population
- Both devices have the same principle of operation and mechanism of action

The subject device and the primary predicate device have the following differences:
The appearance of the Subject device is different with that of the Predicate device. But this difference does not affect the basic safety and essential performance, the subject and the predicate are the same and substantially equivalent.

8.0 Non-clinical Testing

In this current submission, just add four model C101A2, C101B1,C101A3 to the Legally marketed predicate device K173123.
As there were no hardware, software or performance changes made to the subject device when compared to the primary predicate device, no additional non-clinical testing was considered necessary to support the substantial equivalence**.**

Performance Bench Testing
As there are no hardware or software changes as part of this submission from the previous clearance, no performance bench testing was included as part of this submission.

Biocompatibility Testing
As the color of enclosure changes to the patient contacting materials as part of this submission from the previous clearance, biocompatibility testing was included as part of this submission.
The biocompatibility evaluation for the subject device was conducted in accordance with the FDA for Industry and Food and Drug Administration Staff “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing within a risk management process”. The biocompatibility

testing included the following tests:

- Cytotoxicity;
- Irritation;
- Sensitization.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no changes to the hardware or software as part of this submission from the previous clearance, no Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing was included with this submission.

Software Verification and Validation Testing

As there are no software changes as part of this submission from the previous clearance, no software testing was included as part of this submission.

9.0 Clinical Test Conclusion

As the subject device utilizes the same monitoring technology as the predicate device, additional testing was not considered necessary to support the substantial equivalence.

10.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K221979	Predicated Device K173123	Remark
Product Name	Pulse Oximeter	Pulse Oximeter	--
Manufacturer	Shenzhen IMDK Medical Technology Co., Ltd.	Shenzhen IMDK Medical Technology Co., Ltd.	--
Product Code	DQA	DQA	Same
Regulation No.	21CFR 870.2700	21CFR 870.2700	Same
Class	Class II	Class II	Same
Model	C101A2, C101B1, C101A3	C101H1	--
Intended Use/Indication for Use	Fingertip Pulse Oximeter (Model: C101A2, C101B1, C101A3) is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.	Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.	Same
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfuse tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	Same
Applied Population	Adults in a clinic environment	Adults in a clinic environment	Same
Application sites	Finger	Finger	Same
Display Type	OLED	OLED	Same
Display Content	Display the SPO2, PR, pulse bar graph, pulse wave and battery power status	Display the SPO2, PR, pulse bar graph, pulse wave and battery power status	Same
Contacting material	Shell: ABS Clip pad: Silicon Button: PC	Shell: ABS Clip pad: Silicon Button: PC	Same
Overall Dimension	C101A2: 60*36*33mm C101B1: 66*36*33mm C101A3: 58*36*33mm	60*36*35mm	--

Table 2 Performance Comparison

Item	Subject Device K221979	Predicate Device K173123	Remark
LED wavelength	Red= 660 nm; Infrared=904nm	Red= 660 nm; Infrared=904nm	Same
Power source	2 AAA alkaline batteries	2 AAA alkaline batteries	Same
Display data	SpO2%; PR	SpO2%; PR	Same
SpO2 Measuring Range	0%-100%	0%-100%	Same
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	70~100%, ±3%;	70~100%, ±3%;	Same

PR Measuring Range	30-240BPM	30-240BPM	Same
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	±1 bpm or ±1%, whichever is greater	±1 bpm or ±1%, whichever is greater	Same

Table 3 Safety Comparison

Item	Subject Device K221979	Predicate Device K173123	Remark
Electrical Safety	Comply with IEC 60601-1 IEC 60601-1-11	Comply with IEC 60601-1 IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Performance	ISO 80601-2-61	ISO 80601-2-61	Same
Biocompatibility	Cytotoxicity per ISO 10993-5; Irritation per ISO 10993-10; Sensitization per ISO 10993-10	Comply with ISO 10993-1, FDA Guidance	Same

11.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.