December 19, 2025

Shenzhen YKD Technology Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K251751
Trade/Device Name: Spo2 Sensor CSS032D
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 23, 2025
Received: November 25, 2025

Dear Youshan Gong:

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/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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251751

Device Name
Spo2 Sensor (Model: CSS032D)

Indications for Use *(Describe)*
YKD SpO2 sensor (Models: CSS032D) is indicated for continuous non-invasive monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate (PR) in adult patients (>40kg) within medical institutions. It is for fingertip use only and prohibited in emergency medical transport, home care, long-term monitoring, mobile patients, motion, and low perfusion conditions.

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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510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date Prepared: 2025-12-19

I. Submitter

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II. Device

Name of Device: SpO2 sensor
Model(s): CSS032D
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Regulation Number: 21 CRF 870.2700

III. Predicate Device and Reference Device

➢ Predicate Device

Manufacturer	Predicate Device	510(k) Number
JKH USA, LLC	Spo2 Sensor (model: N543-01, U103-01, U103S-01, U403-01, U403S-01, U503-01, U543-01, U410-03, U403-07, U410-02, U403-08, U403-125, U403-06,U410-09, U403S-91)	K202851

IV. Device Description

The SpO2 sensor consist of a probe attached to the patient's finger. The sensor shall be connected to its corresponding pulse oximeter monitor with a data acquisition system which is used to calculate and display oxygen saturation levels and heart rate conditions.

Oxygenation of blood is measured by detecting the infrared and red light absorption characteristics of deoxygenated hemoglobin and oxygenated hemoglobin. The saturation

value is determined by the percentage ratio of the oxygenated hemoglobin (HbO2) to the total amount of hemoglobin (Hb).

As an accessory of the legally marketed oximeters or patient monitors in the United States, the proposed device SpO2 Sensor is intended for hospital use and continuous monitoring of functional arterial oxygen saturation and pulse rate.

V. Indications for Use

YKD SpO2 sensor (Models: CSS032D) is indicated for continuous non-invasive monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate (PR) in adult patients (>40kg) within medical institutions. It is for fingertip use only and prohibited in emergency medical transport, home care, long-term monitoring, mobile patients, motion, and low perfusion conditions.

VI. Materials

Model	Contacted Component Name	Construction Materials
CSS032D	Soft-tip	FEP, Silicone

VII. Comparison of Technological Characteristics With the Predicate Device

The SpO2 sensor has the same intended use as the predicate device. The technological characteristics such as light wavelength, SpO2 measurement rang, SpO2 accuracy, PR measurement range and PR accuracy, are identical to the predicate device. Any minor differences between the subject device and the listed predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.
Therefore, the SpO2 sensor may be found substantially equivalent to its predicate device.

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	K251751	K202851	/
Trade name	Spo2 Sensor	Spo2 Sensor	Same
Model	CSS032D	N543-01, U103-01,	/

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
		U103S-01, U403-01, U403S-01, U503-01, U543-01, U410-03, U403-07, U410-02, U403-08, U403-125, U403-06,U410-09, U403S-91	
Manufacturer	Shenzhen YKD Technology Co., Ltd.	JKH USA, LLC	/
Regulation number	21 CFR 870.2700	21 CFR 870.2700	Same
Product code	DQA	DQA	Same
Device classification	Class II	Class II	Same
Indication for use/ Intended use	YKD SpO2 sensor (Models: CSS032D) is indicated for continuous non-invasive monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate (PR) in adult patients (>40kg) within medical institutions. It is for fingertip use only and prohibited in emergency medical transport, home care, long-term monitoring, mobile patients, motion, and low perfusion conditions.	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 40 kg, pediatric patients weighing 10-50 kg, and neonatal patients weighing no less than 3 kg.	Same
Prescription or OTC	Prescription	Prescription	Same
Clinical study	Clinical studies were conducted to verify the accuracy of subject device. The clinical studies were conducted per following ISO 80601-2-61 and FDA	The subject and predicate devices are exactly the same. Since the sensors are identical, no further clinical testing is necessary.	**Difference** **Note 1**

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
	Guidance. Clinical test results were obtained in human adult volunteers to validate the accuracy of SpO2 Sensors versus arterial oxygen saturation (SaO2) as determined by CO-oximeter. The volunteer population in the studies composed of healthy men and women from age 18 to 33, with variations of skin pigmentations and per FDA's guidance for Pulse Oximeters, three darkly pigmented subjects are included in the clinical study.		
Energy source	Powered by compatible devices	Powered by compatible devices	Same
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light Emitting	Red light LED with wavelength 660-666nm Infrad-light LED with wavelength 880-950nm	Red: 660-666nm, infrared: 880-950nm	Same
Sensor Material	Perfluoro(ethylene-propylene) plastic (FEP), Silicone	ABS, PVC, TPU, Silicone, 3M medical tape and sponge	**Difference** **Note 2**
Distal connector Design	Soft tip	finger clip , soft tip, textile adhesive and sponge non-adhesive	**Difference** **Note 3**
SpO2 Measurement Rang	70-100%	70-100%	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
SpO2 Accuracy	SpO2 Range (70%-100%) --- Accuracy ±3% Arms	±3%	Same
PR Measurement Range	30-250bpm	30-250bpm	Same
PR Accuracy	Accuracy ±3 digits	±3	Same
Usage	Reusable	Reusable and disposable	Same
Applied population	Adult patients weighing greater than 40 kg.	Adult patients weighing greater than 40 kg, pediatric patients weighing 10-50 kg, and neonatal patients weighing no less than 3 kg.	Same
Measurement part	Fingers	Fingers	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Product performance	ISO 80601-2-61	ISO 80601-2-61	Same

Note 1:

The subject device conduct the clinical study to verify the accuracy, and the accuracy of SpO2 and PR is same as predicate device.

Clinical studies were conducted to verify the accuracy of subject device. The clinical studies were conducted per following ISO 80601-2-61 and FDA Guidance.

Clinical test results were obtained in human adult volunteers to validate the accuracy of SpO2 Sensors versus arterial oxygen saturation (SaO2) as determined by CO-oximeter. The volunteer population in the studies composed of healthy men and women from age 18 to 33, with variations of skin pigmentations and per FDA’s guidance for Pulse Oximeters, three darkly pigmented subjects are included in the clinical study.

Note 2:

Though the sensor material of subject device is little different from the predicate device, the material-silicone also used in predicated device. The SpO2 sensor directly contacts with the finger of patient. The material of contacted components of all models are FEP, silicone, which outlined in Section B of Attachment G in Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" released by the FDA on September 8, 2023.

We provide the required information be included in the premarket submission for device types within the scope of the policy outlined in Section D of Attachment G to state we can meet the requirement of this guidance.

Note 3:

Though the Distal connector Design of subject device is different from the predicate device, the textile adhesive and sponge non- adhesive is used for disposable SpO2 sensor of predicated device. The subject device only contain the reusable SpO2 sensor and the distal connector design of reusable SpO2 sensor is same as predicate device, so these difference will not affect the safety and effectiveness of subject device.

Conclusions

SpO2 sensor is substantially equivalent to the predicate device.

VIII. Performance Data

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

1) Biocompatibility Testing

- The biocompatibility evaluation for the body-contacting components of the subject device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-12 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical

electrical equipment and medical electrical systems intended for use in the emergency medical services environment

3) Product performance

- IEC 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

IX. Clinical data

Clinical studies were conducted to verify the accuracy of subject device. The clinical studies were conducted per following ISO 80601-2-61 and FDA Guidance.

Clinical test results were obtained in human adult volunteers to validate the accuracy of SpO2 Sensors versus arterial oxygen saturation (SaO2) as determined by CO-oximeter. The volunteer population in the studies composed of healthy men and women from age 18 to 33, with variations of skin pigmentations and per FDA’ s guidance for Pulse Oximeters, three darkly pigmented subjects are included in the clinical study.

The range of skin pigmentation: II~V from Fitzpatrick scale

The number of tested subjects: The clinical trial was finished with 13 subjects, including 3 males and 10 females, 3 with dark skin and 10 with light skin, ranging in age from 18-33 years old.

The characteristic of subjects distinguished by gender

Index	Female (10)				Male (3)			
	Mean	SD	Min	Max	Mean	SD	Min	Max
Age（years old）	23.70	1.83	21	26	26.33	7.64	18	33
Height（cm）	157.30	5.23	150	165	184.00	19.08	172	206
Weight（kg）	58.15	8.21	47	71.5	91.33	34.43	64	130

Basic characteristics of subjects - by skin color

Index	Light (5)				Medium (5)				Dark (3)			
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max
Age（years old）	24.00	1.41	22	26	23.20	5.72	18	33	26.33	1.53	25	28

Height（cm）	156.80	6.87	150	165	171.40	20.66	155	206	161.33	9.29	155	172
Weight（kg）	56.20	9.01	47	70	73.40	32.09	51	130	68.17	13.81	53	80

Table 39 DUT (CSS032D) adult population test data analysis results - by skin color

Application	skin color	Index/blood oxygen range	[70-100%]	[90 – 100%]	[80 – 90%]	[70 – 80%]
Adult	Light	Number	5	5	5	5
		Datasets	124	54	36	34
		Bias	-0.9	-0.55	-0.04	-0.98
		Sres	1.55	1.14	1.44	1.99
		Arms	1.84	1.79	1.54	2.18
	Medium	Number	5	5	5	5
		Datasets	119	58	36	25
		Bias	-0.7	-0.42	-0.49	-0.71
		Sres	1.6	1	1.54	2.28
		Arms	1.79	1.37	1.75	2.54
	Dark	Number	3	3	3	3
		Datasets	74	33	16	25
		Bias	0.49	-0.62	-0.06	-0.63
		Sres	2.28	1.36	2.31	2.92
		Arms	2.38	1.36	2.5	3.2

Table 40 DUT (CSS032D) adult population test data analysis results - by gender

Application	gender	Index/blood oxygen range	[100-70%]	[90 – 100%]	[80 – 90%]	[70 – 80%]

Adult	Male	Number	3	3	3	3
		Datasets	69	36	18	15
		Bias	-0.79	-0.52	-0.49	-0.45
		Sres	1.39	0.81	1.34	2
		Arms	1.73	1.57	1.55	2.23
	Female	Number	10	10	10	10
		Datasets	248	109	70	69
		Bias	-0.42	-0.65	-0.08	-0.72
		Sres	1.94	1.35	1.86	2.46
		Arms	2.02	1.52	1.9	2.7

Table 41 DUT (CSS032D) adult population test data analysis results - by applicable population

Application	Index/blood oxygen range	[100-70%]	[90 – 100%]	[80 – 90%]	[70 – 80%]
Adult	Number	13	13	13	13
	Datasets	317	145	88	84
	Bias	-0.5	-0.86	-0.38	0.00
	Sres	1.84	1.27	1.78	2.41
	Arms	1.96	1.54	1.83	2.62

X. Conclusions

Based on the above analysis, non-clinical tests and clinical tests performed, it can be concluded that the subject device SpO2 sensor is as safe, as effective, and performs as well as the legally marketed predicate device.