November 27, 2020

JKH USA, LLC
Bill Dai
Manager
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K202851
Trade/Device Name: Spo2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 18, 2020
Received: September 28, 2020

Dear Bill Dai:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202851

Device Name
SpO2 Sensor

Indications for Use *(Describe)*
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.

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

K202851

Submitter:	Name: JKH USA, LLC Mailing Address: 14271 Jeffrey Rd. #246, Irvine, CA 92620
Contact Person:	Name: Bill Quanqin Dai Phone Number: 909-929-9896 Email Address: Bill@jkhUSA.com
Date Prepared:	09/18/2020
Device Trade Name:	Spo2 Sensor
Device Common Name:	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
Classification Names: **Regulation Number:** **Product Code:**	Oximeter 21 CFR 870.2700 DQA
Predicate Device 1: **510(k) Number:** **Device Name:** **Manufacturer:**	 K082546 Unimed compatible oximeter sensors UNIMED MEDICAL SUPPLIES INC
Predicate Device 2: **510(k) Number:** **Device Name:** **Manufacturer:**	 K142832 Unimed Reusable & Disposable Spo2 Sensor UNIMED MEDICAL SUPPLIES INC

Description of Devices:

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.

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).

Four types of sensor housings are described in this submission:

- Reusable soft tip sensor comprised of an integrated silicone rubber tip.
- Reusable finger clip sensor with rigid halves and silicone pads
- Disposable non- adhesive sensor with sponge and velcro backing.
- Disposable adhesive sensors constructed of a medical tape laminate.

Each SpO2 sensor has unique labeling and specifications designed for compatibility with the specific oximeters/monitors that have been legally marketed in the United States. The compatible oximeters/monitors are listed in the labeling of each SpO2 sensor.

Indications for Use:

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, pediatric patients weighing 10-50 kg, and neonatal patients weighing no less than 3 kg.

Comparison to predicate device:

The subject and predicate devices are exactly the same, and there is no difference between them.

Table 1 Substantial Equivalence Table

Description	**Subject Device (K202851)**	**Predicate Device (K082546 and K142832)**
Indications for Use	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.	Unimed Disposable and Reusable 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.
Prescription / over-the-counter use	Prescription	Prescription
Energy source	Powered by compatible devices	Powered by compatible devices
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption
Light Emitting	Red: 660-666nm, infrared: 880-950nm	Red: 660-666nm, infrared: 880-950nm
Sensor Material	ABS, PVC, TPU, Silicone, 3M medical tape and sponge	ABS, PVC, TPU, Silicone, 3M medical tape and sponge
Distal connector Design	finger clip , soft tip, textile adhesive and sponge non- adhesive	finger clip , soft tip, textile adhesive and sponge non- adhesive
SpO2 Measurement Range	70-100%	70-100%

SpO2 Accuracy	±3%	±3%
PR Measurement Range	30-250bpm	30-250bpm
PR Accuracy	±3	±3
Usage	Reusable and disposable	Reusable and disposable
Sterile	Non-sterile	Non-sterile
Biocompatibility contact classification	Surface Skin contact, less than 24hrs	Surface Skin contact, less than 24hrs

Non-clinical test data:

The subject device meets the following the recognized standards:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
- ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity

The proposed device belongs to skin contact, and the contact duration is less than 30 days. Biocompatibility tests have been conducted on the proposed device, including cytotoxicity, sensitization, and skin irritation. The test results show that the proposed device has no issue of cytotoxicity, sensitization, or skin irritation.

Clinical test data:

The subject and predicate devices are exactly the same. Since the sensors are identical, no further clinical testing is necessary.

Substantial Equivalence:

The subject and predicate devices are exactly the same. The sensors are identical to the cleared version and are not modified. Therefore, the subject device is substantially equivalent to the predicate device.