Taiwan Biophotonic Corporation
JC Chen
President
4F-1, No. 6-1, Sec.2, Shengyi Rd.
Zhubei, 30261 Tw

Re: K183556
Trade/Device Name: oCare Wrist Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 18, 2018
Received: December 20, 2018

Dear JC Chen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K183556

Device Name
oCare Wrist Pulse Oximeter, Model Pro 100

Indications for Use *(Describe)*
The oCare Wrist Pulse Oximeter, Model Pro 100, is a wrist-worn device indicated for use in noninvasive measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate (PR). The intended measuring site of this device is the wrist skin surface. It is intended for spot-checking or continuous monitoring of adult patients during no motion conditions, in hospitals, hospital-type facilities, and home environments.

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.

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510(k) Summary

K183556

This 510(k) summary is being submitted in accordance with the requirements of 21CFR 807.92.

1. Submitter Information

Submitter:	Taiwan Biophotonic Corporation
Submitter's Address and Telephone Number	4F-1, No. 6-1, Section 2, Shengyi Road, Zhubei City, Hsinchu County 30261, Taiwan, R.O.C. Phone: +886-3-667-0888; Fax: +886-3-667-0222
Contact Person:	JC Chen, President Phone: +886-3-667-0888 ext.201 e-mail: jc.chen@tbpchc.com
Date Prepared:	November 9, 2018

2. Device Information

Trade Name:	oCare™ Wrist Pulse Oximeter, Model Pro 100
Common Name:	Oximeter
Classification Name	Oximeter
Regulation Number:	21 CFR 870.2700
Regulatory Class:	Class II
Product Code:	DQA

3. Legally Marketed Predicate Devices

The predicates (legally marketed devices) for the subject device (oCare™ Wrist Pulse Oximeter, Model Pro 100) are identified as below:

Primary Predicate: Oxitone 1000, Wrist Pulse Oximeter (K163382)

Reference Device: Nellcor Bedside SpO_2 Patient Monitoring System (K142865).

4. Device Description

The oCare™ Wrist Pulse Oximeter, Model Pro 100 is a wrist-worn device for noninvasive measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate. The intended measuring site of this device is the lateral side of wrist and slightly above the wrist bone (ulnar styloid processus).

The oCare™ Wrist Pulse Oximeter, Model Pro 100 is a watch-like device with a reflectance pulse oximetry sensor located at the bottom of the watch case and on top of the wrist. The reflectance pulse oximetry sensor includes three light emitting diodes (LEDs) of red, infrared and green wavelength and one photodiode light detector placed next to each other. Light beams are emitted from LEDs through the skin to the arteriolar bed of the tissue. Changes in light absorption during the pulsing cycle are measured by the photodiode light detector as scattered lights are reflected back from the pulsating arteriolar bed. The functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate are measured by the well-established non-invasive pulse oximetry technology where the red and infrared light is absorbed in different amounts depending on the oxygenation of the blood during the arterial pulsing. The maximum optical output power is less than 2 mW.

The oCare™ Wrist Pulse Oximeter, Model Pro 100 is a single-patient use, non-sterile pulse oximeter. It is available in one configuration as a standalone device with a wrist pulse oximeter and a detachable watchband for wearing the pulse oximeter on the wrist.

The oCare™ Wrist Pulse Oximeter, Model Pro 100 is a compact and light weight device which consists of a reflectance pulse oximetry sensor, a color graphic OLED display, a lithium ion polymer rechargeable battery, a memory, an analog and digital unit, a microprocessor and an operating software.

The functions of oCare™ Wrist Pulse Oximeter, Model Pro 100 include the following:

(1) Measurement, display and storage of the functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate,

(2) Spot-checking or continuous monitoring of specific physiological parameters,

(3) Built-in memory for up to 72 hours of data storage,

(4) Interface to other health data collection system through the embedded Bluetooth module,

(5) Easy to read 128 x 128 (RGB) color OLED graphic display,

(6) Peripheral micro-USB connector used as the battery charging port,

(7) Built-in rechargeable lithium ion polymer battery,

(8) Pulsing quality indicator and battery power indicator in OLED graphic display,

The proposed device is not for life-supporting or life-sustaining, not for implant.

The device does not contain drug or biological products.

5. Indications for Use

The oCare™ Wrist Pulse Oximeter, Model Pro 100, is a wrist-worn device indicated for use in noninvasive measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate (PR). The intended measuring site of this device is the wrist skin surface. It is intended for spot-checking or continuous monitoring of adult patients during no motion conditions, in hospitals, hospital-type facilities, and home environments.

The subject device has the same intended uses as the predicate Oxitone 1000, Wrist Pulse Oximeter. However, the indications for use of the subject device include additional features as storing and continuous monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate. Although these features are not present in the predicate Oxitone 1000, Wrist Pulse Oximeter, they are present in the reference predicate Nellcor Bedside SpO2 Patient Monitoring System. Thus, it does not constitute a new intended use for the wrist pulse oximeter nor do they different questions of safety and effectiveness for the subject device relative to the predicates.

6. Comparison of Technological Characteristics with the Predicate Devices

The subject device and predicates all use the well-established non-invasive pulse oximetry method to measure the functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate. It is based on two basic principles: (1) oxygenated hemoglobin (HbO2) and deoxygenated hemoglobin (Hb) have different absorption characteristic to red and infrared light; (2) the light absorption by the blood (Hb and HbO2) is cyclic changing by the periodic pulsations of the arterial blood volume during each heartbeat. This periodic changing of light absorption signal is commonly known as the photoplethysmography (PPG).

At a high level, the subject device and predicates are based on the following similar technological elements:

(1) Use of a reflectance pulse oximetry sensor which includes LEDs for emitting light beams through the skin to the arteriolar bed of the tissue, and the photodiode for detecting the PPG signals reflected back from the pulsating arteriolar bed. It has

identical radiant output wavelength of red and infrared and radiant output power of less than 15 mW.

(2) Use of patient contact materials which have been tested to compile with the same standard of ISO 10993 for the category of surface device, intact skin contact and limited contact duration (< 24 hours).

(3) Use of an OLED or LCD display for displaying % SpO_2, pulse rate, battery level indicator and system status.

(4) Use of rechargeable lithium ion polymer battery for the power supply of devices.

(5) The display range, measuring range and accuracy of %SpO_2 provided by the subject device and the predicates are similar.

(6) The display range and measuring accuracy of pulse rate provided by the subject device and the predicates are similar.

The following technological differences exist between the subject device and predicate devices:

(1) The oximetry sensor used by the subject device is configured with three LEDs of red, infrared and green wavelength and one photodiode light detector, but the oximetry sensor used by the predicates is configured with two LEDs of red and infrared wavelength and one photodiode light detector.

(2) The lower limit of measuring rage of pulse rate provided by the predicates is slightly lower than the subject device.

(3) The subject device has an enclosure degree of ingress protection of IPX65, which is better than the enclosure degree of ingress protection of predicates.

(4) The outline dimensions and weight of the subject device is different from the outline dimensions and weight of the predicates.

These different technological characteristics of the subject devices do not raise different questions of safety and effectiveness.

Table 5A - Comparison of Technological Characteristics

Items	Subject Device oCare Wrist Pulse Oximeter, Model Pro 100	Primary Predicate Oxitone 1000 Wrist Pulse Oximeter	Reference Device Nellcor Bedside SpO2 Patient Monitoring System
Type of SpO2 Sensor	Reflectance Optical Sensor	Reflectance Optical Sensor	Reflectance or Transmission Optical Sensor
Application Site	Wrist	Wrist	Finger, Forehead
Output Wavelength and Radiant Power of SpO2 Sensor	Red (655 nm) @ 3.8 mW maximum	Red (640 nm) 1.05 mW	Red (660 nm) @ <15 mW
	Infrared (940 nm) @ 1.7 mW maximum	Infrared (940 nm) 0.95 mW	Infrared (900 nm) @ <15 mW
	Green (530nm) @ 6.9 mW maximum	Not Available	Not Available
Sterility	Non-sterility	Non-sterility	Non-sterility
Display	OLED (128x128 RGB)	LCD, Multi-pixel 3 digits	TFT LCD (480 x 272 pixel)
Display Parameters	SpO2, Pulse Rate, Battery Level Indicator, Pulse Quality Indicator, Alarm Indicator, Time, Date, System Status	SpO2, Pulse Rate, Battery Level Indicator, System Status	SpO2, Pulse Rate, Battery Level Indicator, Signal Quality Indicator, Alarm Indicator, Time, Date, System Status
Mode of Operation	Spot-checking, Continuous Monitoring Data-recording, and Watch Mode	Spot-checking	Spot-checking, Continuous Monitoring, Data-recording
Display Range SpO2 Pulse Rate	 0-100 %SpO2 40-240 bpm	 0-100 %SpO2 30-250 bpm	 0-100 %SpO2 20-250 bpm
Display Resolution SpO2 Pulse Rate	 1% 1 bpm	 1% 1 bpm	 1% 1 bpm

Measuring Range SpO2 Pulse Rate	 70-100 % SpO2 40-240 bpm	 70-100 % SpO2 30-250 bpm	 70-100 % SpO2 20-250 bpm
Measuring Accuracy SpO2 Pulse Rate	 ±3 % SpO2 ±3 bpm	 ±3 % SpO2 ±3 bpm	 ±2 % SpO2 ±3 bpm
Pulse Amplitude Indicator	Not Available. (Readings or dashes give pulse quality indication)	Not Available. (Readings or dashes give pulse quality indication)	Pulse Amplitude Indicator (8-segments)
Data Memory Type Capacity Data Storage Rate	 Non-volatile Up to 72 hours One-second interval	Not Available	 Non-volatile Up to 88000 data event
Alarm	Visual Alarm Indicator	Not Available	Visual and Audio Alarm
Alarm Type	Low Battery Malfunction Poor Signal Condition High/Low SpO_2 /PR	Not Available	Low Battery Technical System Error SpO_2 Sensor Off High/Low SpO_2 /PR
SpO_2 High/Low Alarm Range	High Limit:86-100 %SpO_2 Low Limit:85-95 %SpO_2	Not Available	High Limit: 100 %SpO_2 Low Limit: 90 %SpO_2
PR High/Low Alarm Range	High Limit: 75-240 bpm Low Limit: 40-110 bpm	Not Available	High Limit: 170 bpm Low Limit: 50 bpm
High Priority	Not Available	Not Available	Alarm Indicator: Red Fast Flashing Numeric
Medium Priority	Alarm Indicator: Yellow Alarm Flashing Frequency: 0.4 Hz	Not Available	Alarm Indicator: Yellow Slow Flashing Numeric
Low Priority	Alarm Indicator: Blue Alarm Flashing Frequency: Constant ON	Not Available	Alarm Indicator: Yellow Steady Numeric
Power Supply	Rechargeable Lithium	Rechargeable Lithium	Rechargeable Lithium

	Ion Polymer Battery	Ion Battery	Ion Battery
Battery Charger	Micro USB AB Type	5V AC/DC Adaptor	AC/DC Adaptor
AC Power for Battery Charger	100-240VAC, 50-60Hz, 10VA max	100-240VAC, 50-60Hz, 10VA max	100-240VAC, 50-60Hz, 45VA max
Type of Protection	Internal Powered	Internal Powered	Internal Powered
Degree of Protection –sensor	Type BF – applied part	Type BF – applied part	Type BF – applied part
Enclosure Degree of Ingress Protection	IPX65	Not Available	IP22
Dimension (LxWxH)	Watch Case: 48 x 42 x 14 [mm]	Watch Case 57 x 36 x 18 [mm]	Main Body: 255 x 82 x 155 [mm]
Weight	Watch Case: 25g Watch Band: 33g	Watch Case & Watch Band: 55 g	Main Body: 1600 g including battery
Patient Contact Materials	Patient contact materials have been tested to compile with ISO 10993-1, 10993-3 and 10993-5.	Patient contact materials have been tested to compile with ISO 10993-1, 10993-3 and 10993-5.	Patient contact materials have been tested to compile with ISO 10993-1, 10993-3 and 10993-5.
Interface	Bluetooth	Bluetooth	Not Available
Operating			
Temperature	10 °C to 40 °C	0 °C to 36 °C	5 °C to 40 °C
Humidity	10 % to 93 %, non-condensing;	5 % to 95 %, non-condensing;	15 % to 93 %, non-condensing;
Atmosphere Pressure	760 hPa to 1,060 hPa. (Altitude: 0 ~3,000m)	Not Provided	58 kPa to 103kPa
Storage			
Temperature	-40 °C to 70 °C	-20 °C to 60 °C	-20 °C to 70 °C
Humidity	5 % to 95 %, non-condensing;	Not Provided	5 % to 93 %, non-condensing;

7. Performance Data

Accuracy of pulse oximeter, electrical, mechanical, electromagnetic compatibility, software and biocompatibility testing have been performed on the oCare™ Wrist Pulse Oximeter, Model Pro 100. The results of the testing demonstrate that the subject device is as safe and effective, as the legally marketed predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Testing

Non clinical tests were conducted on the oCare™ Wrist Pulse Oximeter, Model Pro 100 to verify that the subject device met design specifications was substantially equivalent to the predicates.

The test results demonstrated that the subject device complies with electrical safety, electromagnetic compatibility, biocompatibility, software verification and validation, alarm system, usability engineering, battery safety, particulate and water ingress testing, home used medical devices safety and photobiological safety standards.

Test results show that the subject device meets the product specifications including: SpO_2 accuracy without motion of ±3% from 70-100%, and pulse rate of ±3% from 40-240 bpm.

The subject device is considered as skin contacting for duration less than 24 hours. The patient contact materials used by the subject device have been tested to compile with the ISO 10993, and is substantially equivalent to the predicates.

The software for this subject device was considered as a “moderate” level of concern, which is the same as the predicates. Software verification and validation testing were conducted and documentation was provided.

These standards include:

Basic Safety and Essential Performance of Pulse Oximeter	ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
Electrical Equipment Safety and Performance	AAMI/ ANSI ES 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility (EMC)	IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.
EMC for Radio	EN 301 489-1: 2017 Electromagnetic compatibility and radio spectrum

Equipment	matters (ERM) - Electromagnetic compatibility (EMC) Standard for radio equipment and services - Part 1: Common technical requirements
	EN 301 489-17: 2017 Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for broadband data transmission systems
	IEC 62479:2010 Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields. (10 MHz to 300 GHz)
Biocompatibility	ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
	ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: tests for irritation and skin sensitization
Usability	IEC 60601-1-6: 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - collateral standard: Usability
	IEC 62366: 2014 Consolidated version medical devices - Application of usability engineering to medical devices
Alarm System	IEC 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
Safety and Performance of Medical Device Used in Home	IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Lithium Ion Battery Safety	ISO 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
Medical Device Software	US FDA Guidance, No. 337, 2015, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

	IEC 62304:2006 Medical device software–Software life cycle processes
Photobiological Safety	IEC 62471: 2006 Photobiological safety of lamps and lamp systems
Wideband Transmission System	EN 300328:2016 Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
Wireless Telecommunication Requirements	FCC Part 15, Subpart B - Unintentional Radiators
	FCC Part 15, Subpart C - Intentional Radiators
Package	ISTA 2A:2011 Partial Simulation Performance Tests, Packaged-Products weighing 150 lb (68 kg) or Less

Clinical Studies

The SpO_2 accuracy testing of the subject device, oCare™ Wrist Pulse Oximeter, Model Pro 100 has been conducted at an independent research university hospital. The human subjects screened for this testing are health, male, female, no-smoking and light to dark-skinned adult subjects of 20-40 years of age. The non-invasive functional oxygen saturation of arterial hemoglobin (% SpO_2) measured by the subject device were compared to the invasive functional oxygen saturation of arterial hemoglobin (% SaO_2) analyzed by the co-oximetry method with arterial blood samples taken simultaneously. The accuracy of SpO_2 measured by the subject device is evaluated over the SaO_2 range of 70-100% under non-motion condition. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all human subjects, per ISO 80601-2-61, Standard Specification for Pulse Oximeters for Accuracy in a non-motion environment. It demonstrated that the SpO_2 accuracy of the subject device is within ± 3%. There were no reported adverse effects during these investigations.

Objectives: The purpose of this study was to verify the SpO_2 accuracy of the oCare™ Wrist Pulse Oximeter, Model Pro 100 on adult subjects under stationary (non-motion) condition. The measuring site is the wrist. These aims were achieved by comparing SpO_2 measurements with those of arterial blood samples assessed by CO-oximetry. The study was designed in accordance with ISO 80601-2-61. The goal, in its entirety, was to show the SpO_2 accuracy performance for the devices. It was expected that the Accuracy Root Mean Square (Arms) performance of the above pulse oximetry systems will meet a specification of ± 3% for the range of 70-100% SaO_2.

Methods: Human subjects were connected to a breathing circuit, in which the gas flow

delivery was adjusted for the best comfort of human subject. This gas circuit provided a gas mixture of medical grade nitrogen and air. The program was run in manual mode, in which the gas mixture was changed by the controller. The program was used to induce hypoxia in a stair-stepped manner which allowed each human subject to settle at his or her SpO_2 level (e.g. plateau). At each plateau, arterial blood sampling was performed. After drawing a waste sample to clear the arterial line, an arterial sample was drawn. The beginning and end of each draw was noted on the data collection system. This series of waste draw, and arterial draws was repeated multiple times for each plateau. At the end of each plateau, the arterial line was flushed with sterile saline. Subsequently, the program was adjusted to allow the human subject to reach a new level of SpO_2 and the process was repeated.

Conclusions: This subject device, oCare™ Wrist Pulse Oximeter, Model Pro 100 demonstrated a specified accuracy of ± 3% SpO_2 in non-motion conditions on the wrist for all data points with an arterial oxygen saturation (SaO_2) range over 70 – 100 %. Test results show that the subject device meets the product specifications, is substantially equivalent to the predicate Oxitone 1000 Wrist Pulse Oximeter.

8. Conclusions

Based on the clinical data and non-clinical testing summarized in this 510(k) submission, the result demonstrates that the oCare™ Wrist Pulse Oximeter, Model Pro 100 is in compliance with design specifications, applicable standards, and the intended use. The oCare™ Wrist Pulse Oximeter, Model Pro 100 is substantial equivalence to the predicates. The differences do not raise different questions of safety or effectiveness when compared to the predicates.