June 16, 2023

Owlet Baby Care, Inc.
℅ Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K222597
Trade/Device Name: BabySat 3
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 25, 2023
Received: May 25, 2023

Dear Paul Dryden:

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 -S

James J. Lee, PhD
Director
DHT1C: Division of Sleep Disordered Breathing,
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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)*

K222597

Device Name

BabySat 3

Indications for Use *(Describe)*

The BabySat 3 pulse oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse rate. It is indicated for spot-checking and/or continuous monitoring of well-perfused patients greater than one month old up to 18 months old and weighing between 6 and 30 lbs., in the home environment

Type of Use *(Select one or both, as applicable)*

XX 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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Date Prepared: 08-Jun-2023

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Proprietary or Trade Name: BabySat 3
Common/Usual Name: Oximeter
Classification: 21 CFR 870.2700
DQA – Oximeter

Predicate Devices: K182882 - Taiwan Aulisa Medical Devices Technologies, Inc. - Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System
Common/Usual Name: Oximeter
Classification: 21 CFR 870.2700
DQA – Oximeter

Device Description:
The Owlet BabySat 3 is a Pulse Oximeter for use in the home while the baby is resting or sleeping. The Sock secures the Sensor to the baby's foot. The Sensor measures the baby's readings (SpO_2 and Pulse Rate) and transmits the baby's readings to the Base Station directly via Bluetooth. The Base Station monitors the baby's readings and will alarm if the readings are outside prescribed limits. The Base Station also relays the data to the App and to the Owlet servers. The Owlet BabySat 3 mobile device application displays the baby's readings.

The device is stand-alone and not part of a multiparameter module. The device is non-sterile, single patient use reusable and cleanable. The device is not reprocessed.

The BabySat 3 Pulse Oximeter is comprised of several components:

- Sock
  - This holds the sensor in the appropriate place
  - There are 2 size of socks available
  - It is cleanable
- Sensor
  - This is a battery-operated sensor with LED and collects data that is transmitted to the Base Station
- Base Station
  - This is a local unit that has audible and visual alarms which follow the prescribed and pre-set alarm limits for Pulse rate and SpO_2

  - It can transmit data to the Cloud or a mobile device with the downloaded app
- Mobile App
  - This connects with the Base Station via a Wi-Fi local network and allows the individual to monitor and receive messages and alarms remotely

Principle of Operation:
The BabySat 3 sock contains a sensor which uses red and infrared light which is transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood. This data is then used to calculate SpO_2. This is the standard principle of almost all pulse oximeters.

The BabySat 3 Pulse Oximeter measures functional Oxygen Saturation of arterial Hemoglobin (SpO_2) and Pulse Rate. Pulse oximetry measurements are based on two physiological principles: The differences in optical absorbance properties between oxyhemoglobin (HbO_2, oxygenated blood) and deoxyhemoglobin (Hb, non-oxygenated blood). The volume (and therefore light absorption) of arterial blood changes due to heart pulsation as it is distributed in tissue throughout the body.

A Pulse Oximeter determines the saturation of arterially Perfused tissue by sequential illumination with the red (653nm) and infrared (931nm) wavelengths of light via light emitting diodes (LED's). The time-varying signal passing through the tissue is measured from a photodiode detector many times per second, and the differences between the maximum and minimum absorbance due to pulsation are used to determine the saturation, and the pulsation time period is used to calculate the Pulse Rate.

Indications for Use:
The BabySat 3 pulse oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse rate. It is indicated for spot-checking and/or continuous monitoring of well-perfused patients greater than one month old up to 18 months old and weighing between 6 and 30 lbs., in the home environment.

Table 1 – Comparison – Subject vs. Predicate

	Subject Device	**Predicate**	**Comparison**	**Does the difference raise different questions of safety and effectiveness?**
Model:	**BabySat 3**	**GA 1001**		
Manufacturer:	**Owlet, Inc.**	**Taiwan Aulisa Medical Devices Technologies**		
K#	K222597	K182822		
ProCode	DQA - Oximeter CFR 870.2700	DQA - Oximeter CFR 870.2700	Same	No
General Specifications				
Use Environment	Home setting	hospitals, medical facilities, home care, and subacute environments	Similar, with the subject restricted to home use only	No, Subject device has a more limited use environment than predicate.
Patient population	Infant at least 1 month old and up to 18 months old and 6-30 lbs.	Infants and pediatrics	Similar	No, Subject device has a more limited patient population.
Indications for use:	The BabySat 3 pulse oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse rate. It is indicated for spot-checking and/or continuous monitoring of well-perfused patients greater than one month old up to 18 months old and weighing between 6 and 30 lbs., in the home environment	The Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is indicated for spot-checking and/or continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.	Similar	No, Equivalent with exception of the more limited patient population for the subject device. Also, the subject device is not limited to non-motion conditions.

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Contraindications:	- Not for patients under 1 month old or weighing less than 6 pounds - Not for patients older than 18 months or weighing more than 30 pounds - Not a substitute for a caregiver - Not for use as an apnea monitor	-Do not use any part of this system in an MRI environment. -Explosion Hazard: Do not use this system in an explosive atmosphere or in the presence of flammable anesthetics or gasses. -This device is not a replacement for a caregiver.	Similar	No Subject device is for home use only. MRI environments do not need to be contraindicated because they are not found in home environments. Explosive environments are uncommon in the home environment.
Application sight:	Foot	Foot	Same	No
Accessory	Sock with sensor	Sock with sensor	Similar	No
Materials in patient contact	ISO 10993 tested	Unknown	Similar	No Same patient contact
Operating Temperature Range:	5 to 40°C	5 to 40°C	Same	No Equivalent. Specified by 60601-1-11:2015, 4.2.3.1
Storage/Transport Temperature Range:	-25 to 60°C	-25 to 70°C	Similar	No Equivalent. Specified by 60601-1-11:2015, 4.2.3.1
Storage/Transport Atmospheric Pressure:	500 to 1060 hPa	Not specified	Similar	No Based on 60601-1 subclause 7.9.3.1 rationale
Operating Altitude:	≤ 3000 m	≤ 3000 m	Same	No
Operating Atmospheric Pressure:	700 hPa to 1013 hPa	700 hPa to 1013 hPa	Same	No, Equivalent. Specified by 60601-1-11:2015, 4.2.3.1
Operating Humidity:	15 to 90% RH non-condensing	15 to 90% RH non-condensing	Same	No, Equivalent. Specified by 60601-1-11:2015, 4.2.3.1

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Storage/Transport Humidity:	0% to 90 %, non-condensing. Water vapor pressure not to exceed 50hPa.	10% to 93% RH non-condensing	Similar	No Subject device meets requirements specified by 60601-1-11:2015, subclause 4.2.2
Ingress rating:	Sensor: IP35 Base: IP22	IP22	Similar	No Sensor meets more stringent ingress standard.
Alarms				
SpO_2 Upper Limit	Default: Off, Range: 85 to 100	Default: Off, Range: 85 to 100	Same	No
SpO_2 Lower Limit:	Default: 85%, Range: 50 to 95	Default: 85%, Range: 50 to 95	Same	No
Pulse Upper Limit:	Default: 200 BPM Range: 75 to 275	Default: 200 BPM Range: 75 to 275	Same	No
Pulse Lower Limit:	Default: 75 bpm Range: 30 to 110	Default: 75 bpm Range: 30 to 110	Similar	No Min range of 30 bpm is adequate for the patient population of the subject device.
Alarm Silence Duration:	2 min	2 min	Same	No
Alarm Sound Pressure:	55-60 dBA at 1m	60 db	Similar	No
Permanent Alarm Silence:	No permanent alarm silence	Alarm can be permanently silenced	Similar	No
Classification (IEC 60601-1)				
Type of Protection:	Class II	Class II	Same	No
Degree of Protection:	Type BF-Applied Part	Type BF-Applied Part	Same	No
Mode of Operation:	Continuous	Continuous	Same	No

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Wireless Communication				
Transmitter Bluetooth compliance:	BLE 4.0	BLE 4.0	Same	No
Transmitter Operating Range:	30 feet	10 meters	Similar	No
Accuracy and Range				
Oxygen Saturation Range:	1% to 100%	1% to 100%	Same	No
Pulse Rate Range:	30 to 300 bpm	30 to 300 bpm	Same	No
SpO_2 Accuracy:	Non-motion and motion 70-100% +/-3.0% Arms	Non-motion 70-100% ± 3 digits	Same	No Adding motion data
Pulse Rate Accuracy:	Non-motion +/- 3 bpm Arms Motion +/- 5 bpm Arms	± 3 digits	Same	No Predicate not suitable for motion
Sensor Specifications				
Measurement Wavelength/Power (Red):	653 nm, <10 mW max.	660 nm @ 9.8mW	Similar	No Validated by clinical study
Measurement Wavelength/Power (Infrared):	931 nm, <10 mW max	880 nm @ 6.5mW	Similar	No Validated by clinical study
Sensor Internal Battery:	3.8 V	3.7 V	Similar	No

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Sensor Battery Life:	16 hrs	22 hrs	Similar	No risks associated with 12 hour sensor battery life. Base station provides a low priority alarm when sensor battery is getting low. Base station gives a medium priority alarm if the sensor runs out of battery and powers off.
Sensor Weight:	14 grams (with Large sock)	17.5 grams	Similar	No
Sensor Dimensions:	2.2" L x 1.4" W x 0.5" H	5.6” D x 1.2” W x 0.6” H	Similar	No
Base Specifications				
Numeric display:	Mobile device app	10.1" TFT Touch Panel	Similar	No Subject device provides greater ability for view of data through use of app than the Predicate device.
Mains power:	100-240 V AC 50-60 Hz	100-240 V AC 50-60 Hz	Same	No
DC adapter:	5 V	5 V	Same	No
Internal Battery:	3.7V	3.7V	Same	No
Base station battery capacity:	10 min continuous	2 hrs continuous	Similar	No Subject device is not intended to be used deliberately on internal battery power. Base Station battery is for alarm backup only. BabySat 3 alarms continuously when unplugged from power. Alarm continues for 10 minutes, then the BabySat 3 powers itself off.

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Base station Dimensions:	2.4" H x 2.4" L x 0.7" H	7.1" H x 10.8" W x 0.5" D	Similar	No
Base station Weight:	40 grams	750 grams	Similar	No
Biocompatibility	Surface contact Skin Permanent duration of use ISO 10993-5 ISO 10993-10 ISO 10993-11	Surface contact Skin Permanent duration of use	Similar	No Additional ISO 10993-1 testing was performed per Agency feedback
Standards	AAMI ANSI ES 60601-1:2005 + A1: 2012 IEC 60601-1-2: 2014 IEC 60601-1-11: 2015 +AMD1: 2020 IEC 60601-1-8 2020 ISO 80601-2-61: 2017 Wireless coexistence	IEC 60601-1: IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-8 ISO 80601-2-61	Similar	No
SpO2 Accuracy	Desaturation study Non-motion Motion	Desaturation study Non-motion	Similar	No Subject device was also testing for motion
Signal Quality / Intensity	Studied on bench and from Clinical data	Not available	Similar	Subject device included additional testing
ISO 80601-2-61	Pulse Rate Accuracy Pulse Amplitude SpO2 Full Range Performance Environmental Temperature Max Temperature of Applied Parts Signal Quality Scoring	Details not specified	Similar	No

	Subject Device	Predicate	Comparison	Does the difference raise different questions of safety and effectiveness?
Human Factors	Testing performed	Not performed	Similar	No Subject device performed HF testing with lay users
Clinical study	Observational study for skin irritation	Not performed	- -	Subject device performed an observational study for skin irritation

Discussion of Differences and Substantial Equivalence Conclusion

Table 1 above compares the key features of the proposed Owlet BabySat 3 with the identified predicate – K182882 - Taiwan Aulisa Medical Devices Technologies, Inc. - Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System. It demonstrates that the proposed devices can be found to be substantially equivalent.

Indications for Use –
The indications for use are substantively identical for the proposed device when compared to the predicate – K182882 - Taiwan Aulisa Medical Devices Technologies, Inc. - Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System.
Discussion – Each device is indicated for use measuring and monitoring SpO_2 and Pulse Rate. The subject device is more suitable for the infant population with its ability to handle motion.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate - K182882 - Taiwan Aulisa Medical Devices Technologies, Inc. - Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System.
Discussion – The design utilizes transmissions LED, wireless transmission of data and a separate display device, sensor placement on the foot. There are no differences which raise different risk or safety concerns.

Environment of Use –
The environment of use is more restricted as compared to the predicate - K182882 - Taiwan Aulisa Medical Devices Technologies, Inc. - Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System.
Discussion – There are no differences which raise different risk or safety concerns as the subject device has a more limited environment of use.

Patient Population –
The patient population of the subject device is limited to patients greater than 1 month and 6 to 30 lbs. whereas the predicate has been cleared for a larger population.
Discussion – The identified patient population is within the predicate population.

Non-Clinical Testing Summary –

Cleaning / durability –
Cleaning durability testing was performed on the reusable sock and sensor. Tested demonstrated that the components meet there intended service-life and pre-defined acceptance criteria after testing.

Electrical Safety, EMC, RFID and Wireless Co-existence –
The device underwent testing following the following standards:

- AAMI ANSI ES 60601-1:2005 + A1: 2012
- IEC 60601-1-2: 2014
- IEC 60601-1-11: 2015 +AMD1: 2020
- IEC 60601-1-8 2020
- AIM Standard 7351731
- Wireless coexistence

The device met the performance requirements for the intended use and environment.

Software –
Software verification and validation testing was performed and the device met all of its requirements.

Bench testing –
We performed testing in accordance with the applicable standards for safety, EMC. Cleaning, ISO 80601-2-61.
Discussion – The results met the standards. There are no differences which would raise different concerns of risk than the predicate.

Biocompatibility –
Both devices are considered surface contact, intact skin, permanent duration of use (> 30 days).
Discussion – The subject materials were found to meet the applicable requirements for biocompatibility safety for the intended population.

Clinical Testing Summary –

Desaturation testing –
We performed a desaturation study in accordance with FDA guidance and ISO 80601-2-61 and the subject device met the requirement and was similar to the predicate. Testing included subjects across the full Fitzpatrick Scale score.

Signal Quality Study and At Home Study
Signal quality across the intended use population, anatomic size, and location would be acquired and analyzed. The study included comparison to a reference pulse oximeter. The aggregate of data provided covered a full spectrum of evidence supporting the form factor of the Owlet device under review, accuracy related to the gold standard of arterial blood gas measurements, and accuracy in a real world, intended use population against a transfer standard. The evidence

presented demonstrates versatility of the device under review within the intended weight range, age range, and across Fitzpatrick skin tone.

Observational Study
We conducted an Observational study in the intended population for skin irritation and to collect signal quality data.

The primary objective of the study was to estimate the incidence of clinically important skin reactions when instructions for use were followed. Secondary objectives included: an estimation of time for recovery from skin reaction, an estimation of proportion of skin reactions that required medical intervention, and an estimation of incidence of any skin reactions, overall and by severity. The results were that there were no skin irritation events which were considered clinically significant. In addition, we collected signal quality data to support SpO2 accuracy under various use conditions and with a range of patient with Fitzpatrick skin scale. The testing included subjects across the complete Fitzpatrick scale.

Human Factors / Usability
We conducted a Human Factors study following the FDA Guidance with the intended users, lay people, which confirmed successful implementation of all critical tasks.

Discussion of Differences –

The subject device was tested under motion conditions while the predicate was not. We have disclosed the motion performance results and included in labeling what happens to performance under motion conditions.

We provided Signal Quality and Intensity testing which the predicate did not perform. The results were only reportable with no pass / fail criteria.

The observational study was specific to skin irritation, the predicate did not perform such a study. The results supported safe use of the subject device in the intended population and environment.

The differences noted above do not raise different questions of safety.

Substantial Equivalence Conclusion
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.