December 21, 2023

Gabi SmartCare SA
Edouard Carton
COO
Rue Emile Francqui 6
Mont-Saint-Guibert, Brabant Wallon 1435
Belgium

Re: K231531
Trade/Device Name: Pediarity™
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DRG
Dated: May 26, 2023
Received: May 26, 2023

Dear Edouard Carton:

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.

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 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)*
K231531

Device Name
Pediarity™

Indications for Use *(Describe)*
The Pediarity™ system is intended for use in the home setting for spot-checking and/or continuous recording of pulse rate (PR) and functional oxygen saturation of arterial hemoglobin (SpO2) of well-perfused infants and children in non-motion conditions.
The Pediarity™ system is not a monitoring device and does not provide physiological alarms during use.
Measurements are sent to a web server for remote review by a physician.

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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1. SUBMITTER

Submitter Name:	Gabi SmartCare SA
Submitter Address:	Rue Emile Francqui 6, 2nd Floor 1435 Mont-Saint-Guibert - Belgium
Phone Number:	+32 472 53 78 41
Contact Person:	Edouard Carton
E-Mail:	edouard.carton@gabismartcare.com
Date Prepared:	20-DEC-2023

2. DEVICE

Device Trade Name:	Pediarity™
Common Name:	Oximeter
Classification Name:	Oximeter
Regulation Number:	21 CFR 870.2700
Product Code:	DQA
Class:	II
Classification Panel:	Anesthesiology

3. PREDICATE DEVICE

Primary Predicate Device:	Masimo Rad-G Pulse Oximeter and Accessories
510(k) number:	K201770

4. REFERENCE DEVICES

Device Name	WesperO2	Beddr 200 System	Current Health System
510(K) number	K213515	K190399	K231506

5. DEVICE DESCRIPTION

The Pediarity™ system is a non-invasive, innovative, and advanced solution that allows to measure wirelessly several physiological parameters (SpO_2, Pulse Rate) of infants and children up to 12 years old in non-motion conditions.

The Pediarity™ system is composed of:

a) **Gabi™ Band**, a non-invasive, wearable, wireless measuring device positioned around the patient's upper arm.
b) **Gabi™ Monitor**, made of:
   - **Gabi Monitor App**: a mobile application dedicated to caregivers, allowing to start and stop a recording of physiological parameters measured by the Gabi Band, displays measuring information and transfers collected data to the Gabi Cloud via Wi-Fi.
   - **Gabi Monitor Tablet**: a tablet provided to the caregiver inside the solution package, on which the Gabi Monitor App is pre-installed.
c) A **Gabi™ Cloud**, an online service that stores and manages the collected data and shares them with Gabi Analytics.
d) **Gabi™ Analytics**, a web interface allowing the Healthcare Professionals (HCP) to access and review remotely the physiological parameters of the patient.

The Pediarity™ system is illustrated in Figure 1.

Figure 1: Pediarity System components

6. INDICATIONS FOR USE

The Pediarity™ system is intended for use in the home setting for spot checking and/or continuous recording of pulse rate (PR) and functional oxygen saturation of arterial hemoglobin (SpO2) of well-perfused infants and children in non-motion conditions.

The Pediarity™ system is not a monitoring device and does not provide physiological alarms during use.

Measurements are sent to a web server for remote review by a physician.

7. TECHNOLOGICAL CHARACTERISTICS

Pediarity™ uses the principle of pulse oximetry, which is based upon the fundamental principle that hemoglobin bound to oxygen (oxyhemoglobin) and hemoglobin unbound to oxygen (deoxyhemoglobin) absorb light differently. This variation in absorption can then be used to determine the SpO_2. PPG technology is also used to obtain the pulse rate (PR) based on the variation in blood volume in the body.

The sensor uses the non-invasive photoplethysmography (PPG) technology to continuously measure Pulse Rate (PR) and Oxygen Saturation (SpO_2). The technology contains a light source and a photodetector.

Gabi™ Band is applied to the patient's upper arm where the light source emits light to the tissue and the photodetector measures the intensity of reflected light from the tissue. Consequently, this light quantity is less than the one sent by the light source, as some has been absorbed by the tissues and blood. The measurement of motion is enabled by an accelerometer. The signals obtained by the photodetector are then processed and passed to the Gabi™ Monitor App where the values of SpO_2, PR and movement are then displayed.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The comparison chart below provides evidence to facilitate the substantial equivalence determination between the Pediarity™ and the predicate device, Masimo Rad-G Pulse Oximeter and Accessories (K201770) with respect to intended use, technological characteristics and principles of operation.

Table 1: Comparison of subject device to predicate device

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
Device name	Pediarity™	Masimo Rad-G Pulse Oximeter and Accessories	NA
510(k) Number	NA	K201770	NA
Manufacturer	Gabi SmartCare SA	Masimo Corporation	NA
Regulation Number	870.2700	870.2700	Same
Device Class	Class II	Class II	Same
Device Classification Name	Oximeter	Oximeter	Same
Product Code	DQA	DQA	Same
Secondary Product Code	DRG	BZQ, DPZ	Similar Pediarity™ includes DRG as its secondary code as it uses radiofrequency to transmit conditioned physiological signal from one location to another (Gabi Band to Gabi Monitor).

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
			DPZ does not apply to Pediarity™ as the subject device is not intended to be used as an ear oximeter. BZQ does not apply to the Pediarity™ as the subject device is not intended to be used as a breathing frequency monitor. Therefore, this difference does not raise new questions of safety or effectiveness.
Indications for use	The Pediarity™ system is intended for use in the home setting for spot checking and/or continuous recording of pulse rate (PR) and functional oxygen saturation of arterial hemoglobin (SpO2) of well-perfused infants and children in non-motion conditions. The Pediarity™ system is not a monitoring device and does not provide physiological alarms during use. Measurements are sent to a web server for remote review by a physician.	The Rad-G Pulse Oximeter and Accessories are intended for the non-invasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), Pulse Rate (PR), and Pleth Respiration Rate (RRp). The Rad-G Pulse Oximeter and Accessories are indicated for non-invasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments. The Rad-G Pulse Oximeter and Accessories are indicated for the spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in	Similar The subject device intended use includes a subset of the physiological parameters, target population and use environment of the predicate device. Both devices measure physiological parameters in well-perfused infants and children in non-motion conditions. This difference does not raise new questions of safety or effectiveness.

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
		hospitals, hospital-type facilities, transport, and home environments.	
Intended patient population	Infants and children up to and including 12 years of age	Adults and pediatrics (all parameters), Adults, pediatrics, infants and neonates (SpO_2, PR)	Similar The subject device target population is a subset of the predicate device. This difference does not raise new questions of safety or effectiveness.
Anatomical sites	Upper arm	Finger or foot	Similar Both devices are worn to provide device access to peripheral arteries. Differences in wearing location on the body does not raise new questions of safety or efficacy in this case.
Display Type	Gabi™ Monitor Tablet: Touchscreen	Touchscreen	Same
Alarm Type	No physiological alarm	Visual, Audible	Similar The subject device is not intended for continuous vital sign monitoring and is intended to be used outside hospital-type facilities. This difference does not raise new questions of safety or effectiveness.
Technology	Reflectance based oximetry	Transmittance based oximetry	Similar Both technologies rely on the principle that hemoglobin at different oxygenation states absorbs light differently based upon the wavelength of light. Both methods (reflectance and transmittance) are well understood and accepted methodologies to accurately measure SpO_2 and Pulse Rate. The technology difference does not raise new

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
			questions of safety or effectiveness. Additionally, the Beddr 200 System (K190399), an oximeter cleared by the FDA with the same classification and same technology as the subject device, is used to further support the fact that the technology of the subject device does not raise new question of safety and effectiveness.
Supported Parameters	(PR) Pulse Rate, (SpO_2) Oxygen Saturation, Movement	SpO_2, PR, PVi, and RRp	Similar Both devices measure the PR and SpO2. The proposed device also measures the movement, but this is only a secondary feature. Additionally, the subject device does not measure PVi and RRp. This difference does not raise new questions of safety or effectiveness. Additionally, the Current Health System (K231506), a monitoring device cleared by the FDA with the same classification and similar supported parameters as the subject device, is used to further support the fact that the movement parameter use in the subject device does not raise new question of safety and effectiveness.
Display range: SpO_2	70 – 100%	0 – 100%	Similar The predicate device displays a broader range than the predicate device. However, SpO_2 rate under 70% is unlikely for the intended population. This difference does not raise

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
			new questions of safety or effectiveness.
Display range: Pulse Rate	25 – 250 bpm	25 – 240 bpm	Similar The subject device displays similar range as predicate device. Therefore, this difference does not raise new questions of safety or effectiveness.
Display range: Movements	± 2G	None	Similar As mentioned above, the movement is not measured by the predicate device. However, this is only a secondary feature of the subject device. Additionally, the Current Health System (K231506), a monitoring device cleared by the FDA with the same classification and similar supported parameters as the subject device, is used to further support the fact that the movement parameter use in the subject device does not raise new question of safety and effectiveness.
Performance (Arms), non-motion, 70-100%: SpO2	2.95%	2% (Adults/Pediatrics/Infants) 3% (Neonates)	Similar Both devices meet the necessary accuracy requirements for 70-100% related to its technology as indicated in both the FDA guidance on Pulse Oximeter – Premarket Notification Submissions [510(k)s] and the ISO 80601-2-61. This difference does not raise new questions of safety or effectiveness.
Performance (Arms), non-motion: Pulse Rate	3 bpm	3 bpm	Same

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
Environment of use	Home environment	Hospitals, hospital-type facilities, transport, and home environment	Similar The subject device use environment is a subset of the predicate and therefore does not raise new questions of safety and effectiveness.
Operating Temperature	5 – 35°C (41 – 95°F)	0 – 50°C (32 – 122°F)	Similar The subject device Operating Temperature is a subset of the predicate and therefore does not raise new questions of safety and effectiveness.
Operational/Storage Humidity	15 – 90%	10 – 95%, non-condensing	Similar The subject device Operational/Storage Humidity is a subset of the predicate and therefore does not raise new questions of safety and effectiveness.
Operating Atmospheric Pressure	700 – 1060hPa	540 – 1060hPa	Similar The subject device operating Atmospheric Pressure is a subset of the predicate device. This difference does not raise new questions of safety or effectiveness.
Supported Power Source	AC Power or Internal Battery	AC Power or Internal Battery	Same
Internal Battery Type	Rechargeable Lithium Ion	Rechargeable Lithium Ion	Same
AC Power Source	External AC Power Supply	External AC Power Supply	Same
AC Power	Gabi™ Monitor Tablet: 100-240 VAC, 50-60Hz, 0.4A Gabi™ Band: 100-240 VAC, 50-60Hz, 0.2A	100-240 VAC, 50/60 Hz, 0.6A	Similar Different charging currents will lead to different charging times. It was demonstrated in non-clinical performance testing that the speed of charging of the subject device is sufficient to meet the needs of use and its specifications. Such a

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
			difference does not raise new questions of safety or effectiveness.
Network	Wireless (Wi-Fi and Bluetooth)	Wireless (e.g. Wi-Fi, Bluetooth)	Same
Mode of operation	Spot-check and/or continuous data collection	Continuous & Spot-checking	Similar The IFU of the subject device explicitly mentions that it is not a monitoring device, and it does not provide physiological alarms during use, while the predicate device is intended for spot-checking or continuous monitoring and has an alarm function. As mentioned in the FDA guidance on Pulse Oximeters from March 4, 2013, high and low SpO_2 and pulse rate alarms should be included for pulse oximeters intended for continuous monitoring only. This difference does not raise any new safety and effective concerns as the subject device is not intended for continuous monitoring and is not intended to be used in the hospital setting as a monitoring device. Additionally, WesperO2 (K213515), an oximeter cleared by the FDA with the same classification and same mode of operation as the subject device, is used to further support the fact that the mode of operation of the subject device does not raise new question of safety and effectiveness.

Equivalence:

The Pediarity™ is comparable to the predicate device with similar technological characteristics and intended use, specifically to measure physiological parameters in well-perfused infants

and children in non-motion conditions. Both devices can be used in a home environment and both devices use rechargeable lithium-Ion battery. Pediarity™ thus meets the requirements for 510(k) substantial equivalence.

Differences that are demonstrated to be substantially equivalent:

As indicated in Table 1 above, several differences with respect to technological characteristics were identified between Pediarity™ and the predicate device, namely anatomical sites, alarm type, oximetry technology, measured parameters and mode of operation. Performance testing was conducted to demonstrate substantial equivalence of Pediarity™ to the predicate device in terms of safety and performance. The test results are summarized below.

9. PERFORMANCE DATA

Biocompatibility Testing:	The Gabi™ band, which is the only part intended to make direct contact with the patient, was the subject of a range of biocompatibility tests in accordance with ISO 10993-1 including: ● Cytotoxicity, 10993-5:2009 ● Sensitization, 10993-10:2021 ● Irritation, 10993-23:2021 Test results demonstrate that the patient contacting materials meet the biological safety requirements for its categorization. No toxicological hazards are associated with the use of the materials of Pediarity™ and no appreciable toxicological risk are likely to arise from its intended use.
Electrical Safety and EMC testing:	Pediarity™ complies with the IEC 60601-1:2005/AMD2:2021, IEC 60601-1-6:2010, ISO 80601-2-61:2017 standards for safety and the IEC 60601-1-2:2014/Amd1:2021 standard for EMC. Electrical safety testing and Electromagnetic Compatibility testing results show that Pediarity™ meets its specifications.
Software Verification and Validation Testing:	Software verification and validation testing were conducted, and the documentation is provided as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* dated May 11, 2005 and in compliance with ISO 62304:2006/Amd1:2015. The software for this device is considered as a "moderate" level of concern, as defined by the FDA guidance, *Guidance for Industry and FDA Staff – Pulse Oximeters – Premarket Notification Submissions [510(k)s],* dated March 4, 2013, which identifies that a failure or latent flaw in the software could directly result in minor to moderate injury to the patient.
Usability Testing:	Pediarity™ was assessed with regards to usability and complies with IEC 62366-1:2015 + AMD1:2020 – Medical devices – Application of usability engineering to medical devices. The Usability Testing was conducted and the documentation is provided as recommended by FDA's Guidance on *Applying Human Factors and Usability Engineering to Medical Devices*, dated February 3, 2016.

Non-clinical Performance Testing:	Pediarity™ was subjected to bench testing, including pulse rate validation tests to validate the pulse rate feature and to confirm its accuracy in accordance with ISO 80601-2-61:2017 and the FDA Pulse Oximeters - Premarket Notification Submissions: Guidance for Industry and FDA Staff, issued on March 4, 2013 and the performance and safety of PediarityTM. Bench testing also included SpO2 validation tests, to validate the SpO2 feature and to confirm its accuracy over the complete range. Non-clinical Performance Testing results demonstrate that Pediarity™ is safe and effective for the patients considering its intended use.
Clinical Testing:	One clinical study was performed with Pediarity™ to demonstrate substantial equivalence of SpO_2 accuracy with Clause 201.12.1.101.1 of ISO 80601-2-61:2017 as recommended in the FDA guidance on *Pulse Oximeters – Premarket Notification Submissions.* Both clinical studies were conducted in the United States. The clinical test, non-randomized with concurrent ("active") control, performed for measuring SpO_2 was completed on a total of 12 healthy adult male and female volunteers of age 22-30 with different skin pigmentations. All of the subjects enrolled in the study had normal hemoglobin levels (Hemoglobin ≥ 10 $gm*dl^{-1}$). Two devices were used in the study. Hypoxia was induced to different and stable levels of oxyhemoglobin saturation (between 70% to 100%). Blood gas analysis to determine oxyhemoglobin saturation was performed using an ABL-90 multi wavelength oximeter. The obtained SpO_2 accuracy result is 2.95% with a total combined data points of 436 between the two tested devices (at least 200 data points per device). Therefore, the subject device meets the accuracy requirement of less than or equal to 3.5% under no motion condition. The accuracy specification is reported as accuracy root mean square (Arms). Results of the clinical study support the indications for use of Pediarity™, its conformance with ISO 80601-2-61:2011 and substantial equivalence to the predicate device.

10. CONCLUSION

The subject device, Pediarity™, and the predicate device, Masimo Rad-G Pulse Oximeter and Accessories, have an equivalent intended use and the differences in technological features do not raise questions of safety and effectiveness. The information discussed above and provided in the 510(k) submission demonstrate that the Pediarity™ is substantially equivalent to the predicate device.