May 1, 2026

Philips Medizin Systeme
Jamie Palmer
Principal, Regulatory Affairs Specialist
Boblingen Gmbh
Hewlett-Packard St. 2
Boblingen, 71034
Germany

Re: K253887
Trade/Device Name: Nasal Alar SpO2 Sensor (989803205381); Nasal Alar SpO2 Sensor (989803205391); Nasal Alar SpO2 Sensor (989803205401)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 31, 2026
Received: April 1, 2026

Dear Jamie Palmer:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253887

Please provide the device trade name(s).

Nasal Alar SpO2 Sensor (989803205381);
Nasal Alar SpO2 Sensor (989803205391);
Nasal Alar Sp02 Sensor (989803205401)

Please provide your Indications for Use below.

The Nasal Alar SpO2 Sensor is indicated for single patient use, for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate from the nasal ala of adult and pediatric patients (at least 4 years and older and weighing ≥15 kg), who are well or poorly perfused. The sensor can be used in a variety of healthcare environments, where compatible pulse oximetry monitors are indicated for use, under professional supervision.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510K SUMMARY

1. Submitter	
Date Prepared:	29 Apr 2026
Submitter/Owner:	**Philips Medizin Systeme Böblingen, GmbH** FDA Establishment Number: 9610816 Hewlett-Packard Str. 2 Böblingen, 71034 Germany Phone: +49 7031 4630 Fax: 07031-463 -2202
Key Contact:	Jamie L. Palmer Principal, Regulatory Affairs Specialist Jamie.Palmer@philips.com
510(k) Submission Type:	Traditional 510(k)

2. Device	
Trade Name(s):	Nasal Alar SpO2 Sensor (989803205381); Nasal Alar SpO2 Sensor (989803205391); Nasal Alar Sp02 Sensor (989803205401)
Common Name:	Oximeter
Classification Name:	*Device Class*: II (Performance Standards) *Product Code:* DQA (Oximeter) *Regulation Number:* 21 CFR 870.2700 *Review Panel*: Cardiology

3. Predicate Device			
	510(k) No.	***Company Name & Device Name***	***Product Code***
Predicate Device:	K171423	*Company*: Xhale Assurance, Inc. *Device Name*: Nasal Alar SpO_2 Sensor	DQA

The Philips branded Nasal Alar SpO_2 Sensor is substantially equivalent to the legally marketed predicate, Xhale Assurance, Inc.'s, Nasal Alar SpO_2 Sensor cleared via K171423.

4. Device Description [21CFR 807.92 (a) (4)]

The Nasal Alar SpO_2 Sensor is a disposable, single patient use pulse oximetry sensor. It has been designed to attach to the patient's nasal alar region (the fleshy region at the side of the nose) as the nasal ala provides a source of perfusion without the potential physiological interruption of sufficient blood flow that can occur when monitoring distal sites, such as the digits. The Nasal Alar SpO_2 Sensor attaches to the patient's ala via skin contacting, adhesive free, soft, silicone rubber cushions which encapsulate the optical components of the sensor. The Nasal Alar SpO_2 Sensor has been designed for connection to monitors that include or are compatible with Philips FAST SpO_2 technology, utilizing a DB-9 connector cable.

The Nasal Alar SpO_2 Sensor is used as an accessory with the Oximeter (Monitors) as part of a System. The Philips Nasal Alar SpO_2 Sensor comprises three major components; a wire assembly attached to a flexible electrical circuit integrating the LEDs and photodiode; a molded plastic body; and molded silicone rubber cushions that consolidate the assembly and provide the point of skin contact to the patient. An applicator clip is provided with the sensor to allow for application of the sensor on the patient's nasal ala.

5. Intended Use as required per 21 CFR 807.92(a)(5)

The Nasal Alar SpO_2 Sensor is intended for single patient use, for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate from the nasal ala of adult and pediatric patients (at least 4 years and older and weighing ≥15 kg), who are well or poorly perfused. The sensor can be used in a variety of healthcare environments, where compatible pulse oximetry monitors are indicated for use, under professional supervision.

6. Comparison of Technological Characteristics with Predicate Device Acquired by Philips from Xhale Assurance, Inc.	
SIMILARITIES	
Item of Comparison	**Description/Rationale**
Oximeter (Monitor) Type	Those that include or are compatible with Philips FAST (Fourier Artifact Suppression Technology) SpO_2 technology.
Measurement	• SpO_2 • Pulse Rate
Measurement Method	Spectrophotometric measurement of functional arterial oxygen saturation by transmissive mode pulse oximetry.

Biocompatibility Assessment (ISO 10993-1)	Contact Classification Direct and indirect patient contact
Sensor Specifications	• Single-Patient Use • Worn up to 7 days each, 29 days total cumulative use • A_{RMS} range of ≤3% across the range of 70-100% • 30-240 bpm ± 3 bpm
Sensor Storage	-40° to 70°C (-40° to 158°F)
Sensor Shelf-Life	Max 5 years Shelf Life
DIFFERENCES	
Item of Comparison	**Description/Rationale**
Materials	The Nasal Alar SpO_2 Sensor utilizes a new glue formulation, updated colorants for the heat shrink tubing, and a new coverlay material that the Xhale Assurance, Inc, Nasal Alar SpO_2 Sensor predicate device did not. These materials also met the acceptance criteria of testing to ISO 10993-1 and are considered substantially equivalent.
LEDS	A minor adjustment was made to the OPTO SMD Dual LED chip of the Nasal Alar SpO_2 Sensor. This change was designed to improve process yield at the component level, while maintaining the previously established specifications shared with the Xhale Assurance, Inc Nasal Alar SpO_2 Sensor predicate device.
Labeling	Several labeling changes have been implemented. These labeling changes are all updates from the labeling of the Xhale Assurance, Inc. Nasal Alar SpO2 Sensor predicate device.

Ingress Protection Rating	The Nasal Alar SpO_2 Sensor has an ingress protection rating of IP34 which is more stringent than the predicate, Xhale Assurance, Inc Nasal Alar SpO_2 Sensor's rating of IPX1.

SUBSTANTIAL EQUIVALENCE SUMMARY

Operational and technological characteristics form the basis for the determination of substantial equivalence of the Nasal Alar SpO_2 Sensor with the legally marketed predicate device, the Xhale Assurance, Inc Nasal Alar SpO_2 Sensor (K171423).

- The differences do not raise new safety and effectiveness questions as compared to the legally marketed predicate device.
- The minor differences in materials of the subject device do not raise different questions of safety and effectiveness.
- Performance testing was conducted to support the subject device's substantial equivalence to the predicate device.

The Nasal Alar SpO_2 Sensor is a modification of the Xhale Assurance, Inc Nasal Alar SpO2 Sensor (K171423) and therefore is substantially equivalent to the predicate device.

7. Performance Data

Recognized Consensus Standards

The Nasal Alar SpO_2 Sensor has passed all safety tests for demonstrated compliance with the consensus standards listed below:

Standard	FDA Recognition #	Title #
ISO 10993-1	2-258	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5	2-245	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-6	2-247	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation
ISO 10993-10	2-296	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11	2-255	Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
ISO 10993-23	2-291	Biological evaluation of medical devices- Part 23: Tests for irritation
ISO 14971	5-125	Medical Devices – Application of risk management to medical devices
IEC 60601-1	19-49	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	19-36	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6	5-132	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
ISO 14155 2nd Ed	2-282	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 80601-2-61	1-139	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Non-Clinical Tests

1. *Sterilization and Shelf Life*

   Sterilization is **not** applicable to the Nasal Alar SpO_2 Sensor. The subject device is **not** designed to be sterilized.

   The Nasal Alar SpO_2 Sensor is a single-use, single-patient device and is disposed of upon use life or completion of treatment.

   The Nasal Alar SpO_2 Sensor has a defined maximum shelf-life of 5 years. This is supported by V&V testing to ensure product integrity, safety, and device performance over the defined shelf-life period has not been compromised or affected.

2. *Biocompatibility*

   The subject device met the acceptance criteria as defined in the test requirements. Results were deemed as '**PASS**'. There were no unexpected results or significant deviations that would have affected the tests.

   Tests selected were based on contact and duration, as outlined in ISO 10993-1.

   - Cytotoxicity
   - Sensitization
   - Irritation
   - Implantation
   - Acute Systemic Toxicity
   - Subacute/Subchronic Toxicity

   'Irritation' testing was conducted following ISO 10993-10. Based on testing, it was deemed that there was enough data to support the safety of the device without performing additional animal testing as per ISO 10993-2.

3. *EMC, Wireless, Electrical, Mechanical, Thermal Safety and Ingress Protection*

   Prior Electrical Safety and EMC testing of the predicate device, Xhale Assurance, Inc Nasal Alar SpO2 Sensor (K171423) was determined to be representative of the subject device, Nasal Alar SpO2 Sensor after assessment of the modifications.

   The Nasal Alar SpO2 Sensor is connected to the applicable patient monitor via cable and is not capable of wireless communication.

The Nasal Alar SpO2 Sensor was subjected to mechanical and thermal safety testing and was found to perform substantially equivalent to the predicate sensor.

The Nasal Alar SpO2 Sensor and extender cable were evaluated for solid and liquid ingress protection. It was determined that the sensor, when mated with the corresponding SpO2 cable, met the requirements for an ingress protection rating of IP34.

4. *Performance - Bench*

The following Performance Bench Tests were performed:

Test	Test Method	Acceptance Criteria	Result
Pull Test	Comparison of electrical continuity before pulling versus after pulling	0.5V to 0.8V, verified by measuring the forward voltage drop of the diode in the connected probe. 1.5V to 1.8V verified by measuring the forward voltage drop of the LED in the connected probe.	Pass
Shelf-life	Accelerated and real time aging per ASTM F1980	5 years	Pass
Environmental-Reliability	Comparision of force values measured before and after testing	Force Measurement: Force after cycling is equal to the Force before cycling +/- 10%	Pass
DB-9 Mating Force	Analysis of insertion and withdrawal force	Not Applicable – this test was to gather average insertion and withdrawal force of the Alar Sensor DB-9 connector	Not Applicable – this test was to gather average insertion and withdrawal force of the Alar Sensor DB-9 connector
LED Transmission	Measured	LED RED	Pass

	transmission/current of the LED with a 20mA square wave at 1.2kHz	Transmission: Tred < 300 nA/mA LED IR Transmission: TIR < 700 nA/mA	
Pulse Rate	Comparison of displayed readings from the connected monitor versus a simulated pulse rate.	30-240 bpm ± 3bpm	Pass

Clinical Tests:

Clinical SpO_2 testing was conducted per ISO 80601-2-61 to verify the accuracy of the Nasal Alar SpO_2 Sensor. The testing confirmed and overall A_{RMS} of ≤3%.

The data from the non-clinical and clinical testing supports the substantial equivalence of the subject device.

8. CONCLUSIONS

The Nasal Alar SpO_2 Sensor is substantially equivalent to the predicate device in terms of:

- The Indications and Intended Use,
- Operating Principles,
- Conditions of Use, and
- Technological Characteristics.

Verification and Validation (V&V) test results support that the technological characteristics of the Nasal Alar SpO_2 Sensor are substantially equivalent to the predicate device, Xhale Assurance, Inc. Nasal Alar SpO_2 Sensor (K171423). Risk Management activities, V&V testing, and Performance testing were conducted to support the substantial equivalence of the subject device per FDA recognized consensus standards, recognized industry standards, and internal protocol/procedures.