



May 29, 2026

Philips Medizin Systeme Böblingen GmbH
Nicole Söder
Regulatory Affairs Specialist
Hewlett-Packard-Strasse 2
Böblingen, BW 71034
Germany

Re: K252821

Trade/Device Name: Reusable Adult SpO2 Clip Sensor (3m) (M1196A); Reusable Adult SpO2 Clip
Sensor (0.9m) (M1196T)

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: April 30, 2026

Received: April 30, 2026

Dear Nicole Söder:

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.

K252821

?

Please provide the device trade name(s).

?

Reusable Adult SpO2 Clip Sensor (3m) (M1196A)
Reusable Adult SpO2 Clip Sensor (0.9m) (M1196T)

Please provide your Indications for Use below.

?

The Philips Reusable SpO2 Sensors are intended for non-invasive measurement of oxygen saturation (SpO2) and pulse rate. M1196A and M1196T are indicated for patients > 40 kg (typically adult patients).

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)

?

510(k) Summary				
Submitter				
Date Prepared	May 28, 2026			
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany			
Key Contact	Nicole Söder Regulatory Affairs Specialist nicole.soeder@philips.com Phone: +49 (0)7031/463-1492			
510(k) Submission Type	Traditional 510(k)			
Device				
Model Numbers (#)	M1196A & M1196T			
Trade Name	Reusable Adult SpO2 Clip Sensor			
Common Name	SpO2 Pulse Oximeter Sensor			
Classification Name	Panel & Name: Cardiovascular Devices Subpart & Division: 21 CFR §870.2700 Oximeter Regulatory Class: II Product Code: DQA			
Predicate Device				
	510(k) No.	Company	Device Name	Product Code
Predicate Device	K062605	Philips Medical Systems 3000 Minuteman RD. Andover, MA 01810	Philips SpO2 Reusable Sensor, Models M1196A and M1196T	DQA
The subject devices are substantially equivalent to the legally marketed predicate devices.				
Device Description				



Philips Reusable SpO2 Sensors M1196A/M1196T – description of the device per 21 CFR 807.92(a) (4)

The Philips Reusable SpO2 Sensors M1196A/M1196T are used as accessories with compatible Philips Monitor/Defibrillator product lines as part of a System.

These Sensors measure, non-invasively, the arterial oxygen saturation of blood. The measurement method is based on the red and infrared light absorption of hemoglobin and oxyhemoglobin.

The Sensors contain a red and infrared light source and a photodiode receiving the non-absorbed red and infrared light. The received signals are forwarded to a measurement device that amplifies the acquired signal and an algorithm that calculates the ratio and converts via a validated calibration table the ratio to a saturation value.

The Philips Reusable SpO2 Sensors M1196A/M1196T fall into the clip style category. Clip style Sensors follow the traditional SpO2 sensor design of a hard shell, to house the optical components, with a soft, contoured inner material meant to distribute the clamping pressure of the shell.

Intended Use and Indication for Use

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

Intended Use

These sensors are intended to be used by clinicians that have been appropriately trained, such as nurses, physicians, and EMS personnel. These sensors provide continuous, non-invasive measurement of arterial oxygen saturation (pulse rate signal and plethysmograph wave) to any SpO2 device that has passed validation testing. Either sensor can be comfortably clipped onto the finger of patients weighing > 40kg (typically adult patients).

Indications for Use:

The Philips Reusable SpO2 Sensors are intended for non-invasive measurement of oxygen saturation (SpO2) and pulse rate. M1196A and M1196T are indicated for patients > 40 kg (typically adult patients).

Comparison of Technological Characteristics with Predicate Device	
Similarities	
Item of Comparison	Description/Rationale
Intended Use/ Indications for Use/Patient Population	The subject and predicate device do have the same intended use and indications for use. Intended Use/Indications for Use: Subject and predicate device provide continuous, non-invasive measurement of arterial oxygen saturation (pulse rate signal and plethysmograph wave) to any SpO2 device that has passed validation testing. Either sensor can be comfortably clipped onto the finger of patients weighing > 40kg (typically adult patients).
Principle of Operation	The subject and predicate device do have the same Principle of Operation. Spectrophotometric measurement of functional arterial oxygen saturation by transmissive mode pulse oximetry.
Anatomical Sites	The subject and predicate device are applied to any finger except thumb.
Environment of Use	The subject and predicate device are intended for use in hospital environments and for transport to a professional healthcare facility or between professional healthcare facilities.
Sterility	The subject and predicate device are non-sterile
Reusability	The subject and predicate device are reusable devices
Prescription Use	The subject and predicate device are prescription use only devices
Differences	
Material and Color	The subject device is made out of a more matte and opaque material. SpO2 Sensor housing, connector and cable colors have been changed.
LED and Photodiode (PD)	The positioning of the LED and photodiode (PD) was slightly changed for the subject device to optimize the light path.
Calibration Curve	Compared to the predicate device, the subject device applies a different calibration curve. This calibration curve is an existing and known calibration curve, already used in other SpO2 Sensors.
Clinical Study	<p>The 510(k) included clinical data from Philips initiated laboratory tests with the intent to demonstrate the accuracy performance of the subject device.</p> <p>The clinical investigation provides supporting evidence that the proposed design changes tested with the subject device meet the existing SpO2 accuracy (ARMS) claims when validated in a large and diverse patient population.</p>



Substantial Equivalence Summary		
<p>In accordance with 21 CFR Part 807, the Philips Reusable SpO2 Sensors M1196A/M1196T are substantially equivalent to the predicate devices. The differences identified between the subject devices and predicate devices do not raise new questions of safety and effectiveness. Performance testing confirms that the Philips Reusable SpO2 Sensors M1196A/M1196T are substantially equivalent to the predicate devices for Philips Monitor/Defibrillator product lines.</p> <p>The Philips SpO2 Reusable Sensor Models M1196A and M1196T (K062605) serve as the predicate devices.</p>		
Performance Data		
Recognized Standards		
<p>The subject devices have passed all safety tests for demonstrated compliance with the recognized standards below:</p>		
Standard	FDA Recognition #	Title #
IEC 60601-1:2005+A1:2012+A2:2020	19-49	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	1-139	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 62366-1:2015+AMD1:2020:	5-129	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10993-1 Fifth edition 2018-	2-258	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Non-Clinical Bench Testing		
<p>The following Bench tests were performed to demonstrate the correct performance of the Philips Reusable SpO2 Sensors M1196A/M1196T:</p>		



- Interoperability testing, covering the performance between the Philips Reusable SpO2 Sensors and the host monitor device
- Material compatibility testing, covering material resistance to intended use and cleaning and disinfection
- Electronic Hardware testing, covering verification activities related to the applicable calibration curve, testing of optical requirements and testing of ranges, limits and tolerances
- Mechanical testing covering insertion and removal force testing
- Reliability testing covering bending, pull force and stress cycles
- Environmental testing

All above listed testing have met the specified acceptance criteria.

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

Clinical Testing

SpO2 accuracy has been demonstrated through a clinical study performed with the Philips FAST Pulse Oximetry technology and the Philips Reusable SpO2 Sensors.

The performed clinical study is a single-center, non-randomized, desaturation study in healthy adult volunteers. The purpose was to validate the SpO2 accuracy of the Philips FAST Pulse Oximetry System against SaO2 obtained from arterial blood samples and analyzed by CO-Oximetry with consideration to anticipated FDA Guidance for Pulse Oximeters and ISO 80601-2-61 updates.

The testing confirmed and overall ARMS of $\leq 3\%$.

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

Conclusion

Substantial equivalence assessment, based on performance testing and taken together with the clinical study demonstrate that the subject devices do not raise different questions of safety and effectiveness when compared to the predicate device. The Philips Reusable SpO2 Sensors M1196A/M1196T perform as intended and have performance characteristics that are substantially equivalent to the predicate device.