April 4, 2025

Philips Medical Systems Nederland B.V.
David Boser
Director of Regulatory Affairs, Software & Systems
High Tech Campus 34
Eindhoven, 5656 AE
Netherlands

Re: K242001
Trade/Device Name: Philips VitalSigns Camera Medical Library
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: July 9, 2024
Received: July 9, 2024

Dear David Boser:

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.

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242001

Device Name
Philips VitalSigns Camera Medical Library

Indications for Use *(Describe)*

VitalSigns Camera Medical Library is a software library that can be integrated into a customer application for use during virtual consults or health screening. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner as a data point in the overall assessment of the patient. It is used under the supervision of a health care professional, either in the home or in a clinical environment when the subject is still and positioned properly in front of the camera (Samsung Galaxy A20e), which is placed on a stable surface in an adequately lit environment.

It is intended to be used on patients aged 22 years and older that classify as ASA I (American Society of Anesthesiologists), which is defined as a normal healthy patient, non-smoking and no or minimal alcohol use.

It is not intended for continuous patient monitoring system or as the sole method of checking the physical health of the patient, nor as an apnea monitor, but as a part of a framework which mandates periodic checks by a health care professional to ensure appropriate clinical diagnosis and treatment can be reached.

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

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR§807.92.

510(k) Number	K242001	
Date Prepared:	April 2, 2025	
Manufacturer:	Philips Medical Systems Nederland B.V. (**Philips VitalSigns Camera**) High Tech Campus 34 5656 AE Eindhoven The Netherlands	
Primary Contact Person:	David Boser Director of Regulatory Affairs, Software & Systems Email: david.boser@philips.com	
Secondary Contact:	Sabyasachi Roy, PhD Head of Regulatory Affairs - Enterprise Informatics, Innovation & Strategy Email: sabyasachi.roy@philips.com	
Device:	Trade Name:	**Philips VitalSigns Camera Medical Library**
	Classification Name:	Breathing Frequency Monitor
	Classification Regulation:	21 CFR Part 868.2375
	Classification Panel:	Anesthesiology
	Device Class:	Class II
	Primary Product Code:	BZQ (Monitor, Breathing Frequency)
Predicate Device:	Trade Name:	Thora-3Di, Model T-01
	Manufacturer:	PneumaCare, LTD.
	510(k) Clearance:	K151940
	Classification Name:	Breathing Frequency Monitor
	Classification Regulation:	21 CFR Part 868.2375
	Classification Panel:	Anesthesiology
	Device Class:	Class II
	Primary Product Code:	BZQ (Monitor, Breathing Frequency)

Device Description:

The **Philips VitalSigns Camera Medical Library** (hereafter known as **Philips VSC-MEDlib**) is a software library that shall be used in conjunction with a camera which can be part of another platform or as part of a medical device. The **Philips VSC-MEDlib** incorporates an algorithm which allow for automatic, contactless measuring of Respiration Rate (RR).

Philips VSC-MEDlib utilizes the video stream of an unobstructed view of

the subject's torso captured from a camera to calculate the RR from torso motion. The video stream can be captured during a video consult or health screening which should always be conducted in the presence of a physician or other Health Care Professional (HCP). The patient must be properly positioned in front of the camera, sitting still and in an adequately lit environment. From a video stream that typically lasts 60 seconds or less, a spot measurement is taken.

Device Indications for Use:

Philips VSC-MEDlib has the following indications for use:

VitalSigns Camera Medical Library is a software library that can be integrated into a customer application for use during virtual consults or health screening. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner as a data point in the overall assessment of the patient. It is used under the supervision of a health care professional, either in the home or in a clinical environment when the subject is still and positioned properly in front of the camera (Samsung Galaxy A20e), which is placed on a stable surface in an adequately lit environment.

It is intended to be used on patients aged 22 years and older that classify as ASA I (American Society of Anesthesiologists), which is defined as a normal healthy patient, non-smoking and no or minimal alcohol use.

It is not intended for continuous patient monitoring system or as the sole method of checking the physical health of the patient, nor as an apnea monitor, but as a part of a framework which mandates periodic checks by a health care professional to ensure appropriate clinical diagnosis and treatment can be reached.

Device Technological Characteristics:

Philips VSC-MEDlib employs the same fundamental technology as implemented in the currently marketed predicate device, *Thora-3Di, Model T-01* (*K151940*). The fundamental technological are similar, such that both devices analyze video images captured from a digital camera (optical sensor) of a patient positioned in the camera view, to measure their respiratory rate. Both devices analyze torso movement in order to obtain the RR.

Compared to the predicate device:

- *Thora-3Di, Model T-01* is a fully implemented user interface system, whereas **Philips VSC-MEDlib** is not since it is intended to be further integrated into a device from which it would be operated.
- The camera is in a fixed (articulable) installation for *Thora-3Di, Model T-01* whereas in **Philips VSC-MEDlib** it is not.

These differences do not impact the safety and effectiveness of the device, nor do they raise different questions of safety and effectiveness compared to the predicate.

	Subject Device	Predicate Device	Comparison
510(k) #	K242001	K151940	N/A
Device Name	Philips VitalSigns Camera Medical Library	Thora-3Di, Model T-01	N/A
Common Name	VitalSigns Camera	Thora-3Di	N/A
Manufacturer	Philips Medical Systems Nederland B.V.	PneumaCare, Ltd.	N/A
Indications for Use	VitalSigns Camera Medical Library is a software library that can be integrated into a customer application for use during virtual consults or health screening. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner as a data point in the overall assessment of the patient. It is used under the supervision of a health care professional, either in the home or in a clinical environment when the subject is still and positioned properly in front of the camera (Samsung Galaxy A20e), which is placed on a stable surface in an adequately lit environment. It is intended to be used on patients aged 22 years and older that classify as ASA I (American Society of Anesthesiologists), which is defined as a normal healthy patient, non-smoking and no or minimal alcohol use. It is not intended for continuous patient	The Thora-3Di is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider. The Thora-3Di is not intended to monitor vital signs. This device is not an apnea monitor.	Substantially Equivalent Both devices: • Are intended for spot check measurement of Respiratory Rate (RR) in a non-invasive manner. • Are not intended for continuous monitoring; • Implement an algorithm to provide the RR measurement and are not the sole method of checking the health of a subject but as an adjunct to traditional methods; and • Are intended for use in adults only.

	monitoring system or as the sole method of checking the physical health of the patient, nor as an apnea monitor, but as a part of a framework which mandates periodic checks by a health care professional to ensure appropriate clinical diagnosis and treatment can be reached.		
Component	Software Only	Fully Integrated System	Differences do not raise new/different questions of safety or effectiveness.
Patient Type	Healthy (ASA I classified) Adults not requiring critical care	Adults	Substantially equivalent "Healthy (ASA I) Adults not requiring clinical care" is a lower-risk subset of "adults" such that no new questions of safety/effectiveness arise.
Use Environment	Home and Hospital setting	In hospital or clinical care settings.	Similar; The addition of Home use does not raise new/different questions of safety or effectiveness. Reference device to support substantial equivalence of home use -K223163
Respiration Rate Measurement Range	7-30 bpm	8-25 bpm	Substantially Equivalent
Accuracy (Error/Tolerance)	±3 bpm	±2 bpm	Substantially Equivalent
Measurement Window	60 seconds	60 seconds	Same

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **Philips VSC-MEDlib,** demonstrating compliance with the following FDA recognized consensus standards and FDA guidance document(s):

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79,
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.0, 2015-02). FDA/CDRH recognition number 5-114,
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition. 3.0, 2019-12). FDA/CDRH recognition number 5-125,
- *"Guidance for Industry and FDA Staff - Content of Premarket*

Submissions for Device Software Functions", June 14, 2023 (document number 0775),
- *"Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices",* February 3, 2016 (document number 1757),
- *"Guidance for Industry and FDA Staff – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions",* September 27, 2023 (document number 1158),
- *"Guidance for Industry and FDA Staff – Off-The-Shelf Software Use in Medical Devices",* August 11, 2023 (document number 3598),
- *"Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]",* July 28, 2014 (document number 1766).

Non-clinical software verification testing has been performed to verify that all functional and nonfunctional requirements of the Product Requirements Specification, as well as the identified safety Risk Control Measures from the Safety Risk Assessment Matrix and the and Security requirements for **Philips VSC-MEDlib** have been implemented.

Software validation testing has been performed to validate that **Philips VSC-MEDlib** conforms to its intended use, user (customer) needs. The validation consisted of the following activities:

- Usability validation was performed with both HCPs and lay users in a simulated use environment. **Philips VSC-MEDlib** was found to be safe and effective for the intended use, users and use environment.
- The algorithm implemented in **Philips VSC-MEDlib** was evaluated in the clinical study described below.

Additional testing performed:

- Lighting Frequency Testing comparing the performance of the device under various lighting conditions such as fluorescent, LED and incandescent lamps connected to 50 Hz and 60 Hz mains power.

Summary of Clinical Performance Data:

A single center, prospective clinical investigation was conducted in the Netherlands to evaluate the accuracy of the **Philips VSC-MEDlib** for measuring RR compared to gold standard reference devices (manually annotated capnography) in breaths per minute (BPM).

The subject population was representative of the intended U.S. population. It was balanced across sex, age, body mass index (BMI) and was designed to represent the intended use population in the intended use environment. The study also evaluated the performance under suboptimal conditions of use, including those presenting challenging data quality including but not limited to makeup, facial obstructions (e.g., sunglasses), various camera lens conditions (e.g., cracked, shattered, sanded), thereby demonstrating the effectiveness of the risk control measures of the device.

The table below shows detailed information on the demographics of the study population:

Variable	Enrolled population (n=92)
Age [years]	
Average	42.0 (18-73)
18-22	4 (4.4%)
22-30	15 (16.3%)
30-40	22 (23.9%)
40-50	22 (23.9%)
50-60	18 (19.6%)
60-73	11 (12.0%)
Gender	
Male	44 (47.8%)
Female	48 (52.2%)
Other	0 (0.0%)
BMI [kg/m^2]	
Average	26.1 (18-39)
18-25	42 (45.7%)
25-30	36 (39.1%)
30-35	8 (8.7%)
35-40	6 (6.5%)

VSC-MEDlib provided a RR output for 83 subjects (93.3%). RMSE was 0.80 [95% CI = 0.582 – 1.017], which meets the primary endpoint of ≤ 3 BPM.

Substantial Equivalence Conclusion:

Philips VSC-MEDlib is substantially equivalent to the currently marketed predicate device *Thora-3Di, Model T-01* (*K151940*) because it has a similar intended use, similar indications for use, and similar technological characteristics. Differences between the devices do not raise new questions regarding safety or efficacy compared to the predicate device. Moreover, the submitted non-clinical and clinical testing, support the substantial equivalence of the **Philips VSC-MEDlib**.