April 30, 2026

Ambu A/S
% Sanjay Parikh
Senior Director, QA/RA
Ambu Inc.
6721 Columbia Gateway Drive
Suite 200
Columbia, Maryland 21046

Re: K251583
Trade/Device Name: Ambu® Virobac II® Exhalation Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: August 22, 2025
Received: April 1, 2026

Dear Sanjay Parikh:

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,

Dolly Singh Digitally signed by Dolly Singh

For Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control 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.

Submission Number *(if known)*

K251583

Device Name

Ambu® Virobac II® Exhalation Filter

Indications for Use *(Describe)*

The Virobac II® Exhalation Filter is a viral/bacterial filter intended for use when the care provider desires to prevent the transmission of viruses or bacteria from patients receiving respiratory support.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K251583

Date Prepared	30-April-2026
Company Name and Address	Ambu A/S Baltorpbakken 13 DK-2750 Ballerup Denmark Tel: +45 7225 2000
Prepared and Submitted by:	Lenka Vaculčiaková Regulatory Affairs Professional Tel: +45 7225 2837 Email: leva@ambu.com
Official Contact:	Sanjay Parikh Senior Director, QA/RA Address: Ambu Inc. 6721 Columbia Gateway Drive, Suite 200 Columbia, Maryland 21046 Tel: +1 443 831 9844 Email: sap@ambu.com
Applicant Device	
Trade Name:	Ambu® Virobac II® Exhalation Filter
Common Name:	Viral/Bacterial Filter
Classification Name :	21 CFR § 868.5260, Breathing circuit bacterial filter
FDA Product Code:	CAH
Regulatory Class:	II
Type of Submission:	Traditional
Predicate Device	
Trade Name:	Mercury Medical CPR Bag Exhalation Filter
510(k) Number:	K954490 This predicate has not been subject to a design-related recall, according to FDA's Medical Device Recall database.
Manufacturer Name:	Mercury Medical Superior Solutions
Reference Device	No reference devices were used in this submission.

1. Device Description

The Ambu® Virobac II® Exhalation Filter is a stand-alone, non-sterile, single patient use viral/bacterial filter.

The Ambu® Virobac II® Exhalation Filter is intended for use when the care provider desires to prevent the transmission of viruses or bacteria from patients receiving respiratory support. The Ambu® Virobac II® Exhalation Filter is used in connection with a resuscitator to filter patient expiratory air during resuscitation. It connects to the resuscitator by a standard ISO conical connection and is comprised of a compact transparent housing with filter media.

2. Intended Use / Indications for Use

The Virobac II® Exhalation Filter is a viral/bacterial filter intended for use when the care provider desires to prevent the transmission of viruses or bacteria from patients receiving respiratory support.

3. Comparison of Technological Characteristics with the Predicate Device

	Applicant (K251583) Ambu® Virobac II® Exhalation Filter	**Predicate Device (K954490)** Mercury Medical CPR Bag Exhalation Filter	**Substantial equivalence assessment**
	REGULATORY INFORMATION		
Manufacturer	Ambu A/S	Mercury Medical Superior Solutions	N/A
Device trade name and model no.	Ambu® Virobac II® Exhalation Filter	Mercury Medical Exhalation Filter	N/A
Device depiction			N/A
510(k) number	K251583 - application	K954490	N/A
Product code	CAH		Same
Regulation description	Filter, Bacterial, Breathing-Circuit		Same
Regulation number	868.5260		Same
Device Classification	Class II		Same
	USE OF PRODUCT		
Intended use/Indications for use	The Virobac II® Exhalation Filter is a viral/bacterial filter intended for use when the care provider desires to prevent the transmission of viruses or bacteria from patients receiving respiratory support.	The filter is intended to remove microbiological and particulate matter from the gases in the breathing circuit.	Equivalent to predicate (Ref. Note 1)
Target population	Adult and Pediatric patients undergoing resuscitation.	Not stated	Not stated for predicate (Ref. Note 2)
Device configuration	Straight		Same

	Applicant (K251583) Ambu® Virobac II® Exhalation Filter	**Predicate Device (K954490)** Mercury Medical CPR Bag Exhalation Filter	**Substantial equivalence assessment**
Rx Only	Yes		Same
	TECHNOLOGICAL CHARACTERISTICS and SPECIFICATIONS		
Principle of Operation	Electrostatic filtration method		Same
Materials: - Housing - Filter	Housing: Methyl Methacrylate Butadiene Styrene Filter media: Polypropylene fibers	Housing: Clear Filter media: Proprietary spun polypropylene	Equivalent to predicate (Ref. Note 3)
Connectors	Standard conical connectors ID 30 mm and OD 30 mm according to ISO 5356-1 and ISO 10651-4 (30 mm)	Standard conical connectors 30 mm I.D. (per ISO 5356-1) x 30 mm O.D.	Same
Delivered sterile	No		Same
Device use designation	Single patient use		Same
MR designation	MR safe		Same
	GENERAL PERFORMANCE		
Bacterial/ Viral Filtration Efficiency	BFE: ≥ 99.99% VFE: ≥ 99.99%	BFE: 99.96% effective on particles with an approximate size of 3.1 microns VFE: 99.81% effective on particles with an approximate size of 3.3 microns	Equivalent to predicate (Ref. Note 4)

Note 1: Intended Use/Indications for Use
Both the applicant and predicate devices are designed to perform the same clinical function: the removal of microbiological and particulate matter. Both are used in similar clinical contexts (manual and mechanical ventilation) and are intended to reduce the risk of cross-contamination. The directions for use further confirm that the devices are functionally and operationally equivalent, explicitly listing the use on manual hand resuscitation exhalation ports. Therefore, the intended use is considered equivalent.

Note 2: Target population
There is no specified target population for the predicate device. However, based on the resuscitation catalog matrix by Mercury Medical, the Exhalation filter is being used together with ADULT, CHILD and INFANT BVM BAGS. Additionally, both applicant and predicate devices are attached to the expiratory port and thus do not contribute to mechanical dead space affecting gas exchange and ventilation efficiency. Therefore, specifying target population as ‘adult and pediatric patients undergoing resuscitation’ for the applicant device is considered equivalent to the predicate device.

Note 3: Materials
Both applicant and predicate devices use a multi-layered filter media material comprising of layers of polypropylene. The proprietary material of the predicate filter media is electrostatically charged to aid in attraction of particles. The applicant device has been tested to show viral filtration efficiency/bacterial filtration efficiency of at least 99.99%, which is similar to the efficiencies stated for the predicate device.

The filter housings of both devices are comprised of clear, rigid plastic material with an upper and lower portion, thus considered equivalent. Methyl Methacrylate Butadiene Styrene material has enhanced clarity for aesthetic purposes and is commonly used in anesthesia devices.

Note 4: Bacterial/ Viral Filtration Efficiency
Testing of the applicant device was performed by Nelson Laboratories, LLC. The particle size was 3.0 ± 0.3 µm. The applicant device complies with ISO 23328 –1 and ASTM F2101 standards. The measured BFE and VFE are equivalent, or better than the predicate device.

4. Non-Clinical Tests Summary

Test Standards	Test Performed	Acceptance Criteria	Results
ISO 23328-2	Resistance	Resistance shall be less than 1.2 cm H_2O at 30 l/min (0.5 L/sec) and 15 l/min (0.25 L/sec)	Pass
	Duration of Use	Resistance shall be less than 1.2 cm H_2O at 30 l/min (0.5 L/sec) and 15 l/min (0.25 L/sec)	Pass
	Leak	Filter shall not leak more than 10 ml/min at 70 cm H2O ± 3.5 cm H2O	Pass
	Volume	Volume shall be less than 80 ml	Pass
N/A	Miscellaneous Inspections	No sharp edges. No visual defects. Presence of internal ribs preventing attachment to the ID of 30 mm OD connection. Flash ≤ 0.25 mm Internally and ≤ 0.50 mm Externally	Pass
	Weight	Weight shall be less than 31 g	Pass
ISO 5356-1 ISO 10651-4	ISO connections	Connections shall meet ISO 5356-1 and ISO 10651-4 B.4.2	Pass
ASTM F2101	Bacterial/Viral Filtration efficiency	Product shall remove 99.99% of bacteria and viruses	Pass
ISO 23328-1	NaCl Filtration	Product shall be tested according to ISO 23328-1: Salt test method to assess filtration performance. Testing shall be conducted prior to BFE/VFE testing.	Pass
ASTM D4169	Transportation study	Product shall function after transport simulation using ASTM D4169 assurance level II	Pass

5. Conclusions

Based on the intended use, technological characteristics and the non-clinical performance tests, the subject device demonstrates substantial equivalence to the predicate device.