May 8, 2025

Telesair Inc.
℅ Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
Saint Petersburg, Florida 33704

Re: K251133
Trade/Device Name: AVEA disposable expiratory filter/water trap (11790)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: April 11, 2025
Received: April 11, 2025

Dear Paul Dryden:

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,

Ethan L. Nyberg -S

Ethan Nyberg, 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)*
K251133

Device Name
AVEA Disposable Expiratory Filter/Water trap

Indications for Use *(Describe)*
The AVEA Disposable Expiratory Filter/ Water Trap is an expiratory filter and water trap for use with the AVEA Ventilator.

It would be used in an institutional healthcare environment (e.g., hospitals). It may be used on adult, pediatric, and neonatal patients.

It should be operated by properly trained clinical personnel, under the direction of 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.

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

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Date Prepared:	23-Apr-25
Sponsor:	Telesair Inc. 199 Technology Drive, Suite 110 Irvine, CA 92618 Tel - 949-570-3553
Sponsor Contact:	Don Lin, Ph.D. - Founder and CEO
Submission Correspondent:	Paul Dryden ProMedic Consulting LLC
Proprietary or Trade Name:	AVEA disposable expiratory filter/water trap
Common/Usual Name:	Ventilator, continuous, facility use
Classification Name:	Continuous Ventilator 21 CFR 868.5895
Product Code:	CBK
Proprietary or Trade Name:	AVEA disposable expiratory filter/water trap
Common/Usual Name:	Ventilator, continuous, facility use
Classification Name:	Continuous Ventilator 21 CFR 868.5895
Product Code:	CBK
Device Description	The AVEA disposable expiratory filter/water trap is designed to be used exclusively with the AVEA Ventilator.
Indications for Use:	The AVEA Disposable Expiratory Filter/ Water Trap is an expiratory filter and water trap for use with the AVEA Ventilator. It would be used in an institutional healthcare environment (e.g., hospitals). It may be used on adult, pediatric, and neonatal patients. It should be operated by properly trained clinical personnel, under the direction of a physician.

Table of Comparison of Subject vs. Predicate

	Predicate Vyaire AVEA Disposable Expiratory Filter/ Water Trap	Subject device AVEA Disposable Expiratory Filter/ Water Trap	Comparison
K#	K081837	TBD	
Product Code	CBK	CB	Identical
CFR	868.5895	868.5895	Identical
Indications for Use	The AVEA Ventilator is intended to provide continuous respiratory support in an institutional healthcare environment (e.g. hospitals). It may be used on adult, pediatric, and neonatal patients. It should be operated by properly trained clinical personnel, under the direction of a physician. This is the same intended use as previously cleared for AVEA under K013642, K022674, and K062093. There is no change to the AVEA intended use.	The AVEA Disposable Expiratory Filter/ Water Trap is an expiratory filter and water trap for use with the AVEA Ventilator. It would be used in an institutional healthcare environment (e.g., hospitals). It may be used on adult, pediatric, and neonatal patients. It should be operated by properly trained clinical personnel, under the direction of a physician.	Clarified the indications to be specific for the filter as an accessory to the Avea ventilator. Otherwise similar.
Fundamental scientific technology	Filtration media with integral water trap	Filtration media with integral water trap	Identical to K081837
Bench testing	Testing was not listed in K081837	Identical to K081837	Identical to K081837
Performance as listed on labeling	VFE / BFE 99.999% DOP / POA efficiency 99.97% Flow resistance - < 1 cmH2O at 60 lpm Flow leakage - <0.01 lpm at 140 cmH2O internal pressure	VFE / BFE 99.999% DOP / POA efficiency 99.97% Flow resistance - < 1 cmH2O at 60 lpm Flow leakage - <0.01 lpm at 140 cmH2O internal pressure	Identical to K081837

	Predicate Vyaire AVEA Disposable Expiratory Filter/ Water Trap	Subject device AVEA Disposable Expiratory Filter/ Water Trap	Comparison
Internal volume	500 ml includes Water trap of 130 ml	500 ml includes Water trap of 130 ml	Identical for K081837
Dimensions	Diameter – 9.7 cm Height – 33 cm	Diameter – 9.7 cm Height – 33 cm	Identical to K081837
Biocompatibility	Tested per ISO 10993	Tested per ISO 10993	Identical to K081837

Substantial Equivalence Discussion

The subject and predicate devices are identical in all ways.

Intended Use/ Indications for Use

The indications for use for the subject device have been updated to reflect this as an accessory to the AVEA ventilator only. Otherwise, the intended use is the same as AVEA disposable expiratory filter/water trap cleared under K081837.

Substantial Equivalence Conclusion

The subject device and the predicate – AVEA disposable expiratory filter/water trap – K081837 is substantially equivalent based upon identicality.