August 13, 2026

Aw Technologies Aps
Jorgen Hansen
QARA Manager
Amalienborgvej 57
Norresundby, 9400
Denmark

Re: K261499
Trade/Device Name: TrachFlush
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: July 10, 2026
Received: July 10, 2026

Dear Jorgen Hansen:

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

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)*
K261499

Device Name
TrachFlush

Indications for Use *(Describe)*

The TrachFlush device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.

The TrachFlush device is also intended to assist in clearing upper airway secretions by simulating an artificial cough during mechanical ventilation.

The TrachFlush device can be used with any mechanical ventilator.

The TrachFlush device is to be used during ventilation of adults at least 18 years who are intubated with ETT or TT, in the following areas:

• In the intensive care ward by Respiratory Therapist

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 in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

AW Technologies Aps
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Denmark
Tel.: +45 51 26 18 27
ash@trachflush.com

Contact Person: Mr. Adam Hansen

Position/Title: CEO

Date of Preparation: July 7, 2026

(2) **Trade Name:** TrachFlush

Common/Classification Name: Cuff, Tracheal Tube, Inflatable

Product Code(s): 21 CFR §868.5750; BSK

Class: Class II

(3) **Predicate and Reference Device:**

Substantial Equivalence to:

Type	K Number	Model	Manufacturer
Predicate Device	K220854	TrachCuff cuff controller	AW Technologies, Denmark
Reference Device	K121955	CoughAssist T70/E70	Philips Respironics Inc, USA

Reason for Submission: **Labelling change** – Indications for Use update and new Trade/Product name

(4) **Description of Device:**

The TrachFlush device is an automatic cuff pressure controller specified for use in professional healthcare environments. The device provides the operator with the means to set and control the pressure for cuffed endotracheal tubes and cuffed tracheostomy tubes during mechanical ventilation, and continuous monitoring of the set cuff pressure with alarms.

The TrachFlush device is mains powered via a Mains to DC power adapter, and the enclosure may be mounted on a bed rail by means of an optional mounting bracket.

The TrachFlush device is provided in an enclosure with touch screen operator panel.

It is designed for immediate use; no calibration or maintenance is required. A large-scale display and convenient and intuitive interaction buttons maximize safe use and visibility of all important data.

The associated accessories include:

- Disposable Tubing Set with Filter
- Device Mount Solution – Bedside Mounting Bracket.

(5) Intended use:

The intended use for the TrachFlush device is the same as the predicate device: to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.

Indications for Use:

The TrachFlush device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.

The TrachFlush device is also intended to assist in clearing upper airway secretions by simulating an artificial cough during mechanical ventilation.

The TrachFlush device can be used with any mechanical ventilator.

The TrachFlush device is to be used during ventilation of adults at least 18 years who are intubated with ETT or TT, in the following areas:

- In the intensive care ward by Respiratory Therapist

Prescription use only.

(6) Technological Characteristics:

The TrachFlush device utilizes exactly the same device as the predicate device to continuously measure and automatically maintain the user-set cuff pressure of an ETT or TT.

Comparison of Technological Features to the Predicate Device and the Reference Devices:

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
General Information				
Manufacturer	AW Technologies ApS	AW Technologies ApS	Same	
Model Number Device	Cuff Controller: AWT-2001	Cuff Controller: AWT-2001	Same	
Model Number Disposable	Tubing Set: SACO02	Tubing Set: SACO02	Same	
Product Name	TrachFlush	TrachCuff	Different	New product name
Product Code	BSK	BSK	Same	
Regulation Number	21 CFR §868.5750	21 CFR §868.5750	Same	
FDA Clearance	K261499	K220854	Different	New clearance
Classification Name	Cuff, Tracheal Tube, Inflatable	Cuff, Tracheal Tube, Inflatable	Same	
Prescription Device	✓ YES	✓ YES	Same	
Patient Population(s)	Adults at least 18 years who are intubated with ETT or TT	Adults at least 18 years who are intubated with ETT or TT	Same	
Cuff Controller Device is Reusable	✓ YES	✓ YES	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Cuff Controller Tubing Set is single use disposable	✓ YES	✓ YES	Same	
Accessory Tubing provided sterile	No	No	Same	
Intended Use (IU) including Indications for Use (IFU)				
Indications for Use	The TrachFlush device is intended to continuously measure and automatically maintain the use-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation. The TrachFlush device is also intended to assist in clearing upper airway secretions by simulating an artificial cough during mechanical ventilation	The TrachCuff device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation. N/A	Same Different to PD Same to RD	The Indications for Use Statement for the Subject Device contains an additional statement for assisting in clearing secretions which is equivalent to the Reference Device
Patients, Users and Environment				
Patients	The TrachFlush is to be used during ventilation of adults at least 18 years who are intubated with ETT or TT	The TrachCuff is to be used during ventilation of adults at least 18 years who are intubated with ETT or TT	Same	
User	Respiratory Therapist	Respiratory Therapist	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Environment of Use	In the intensive care ward	In the intensive care ward	Same	
Contraindications	None	None	Same	
Device Description				
Use/Application	Continuously measure and automatically maintains user-set ETT or TT cuff pressure during mechanical ventilation The TrachFlush device can also assist in clearing upper airway secretions.	Continuously measure and automatically maintains user-set ETT or TT cuff pressure during mechanical ventilation N/A	Same Different to PD Same to RD	The Use/Application for the Subject Device contains an additional feature for clearing secretions by simulating a cough which is equivalent to the Reference Device
Device Image			Similar	New product name on Device

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Operating Modes/Sequences	Automatic maintenance of set Cuff Pressure Operator-initiated change of set Cuff Pressure Operator-initiated time-limited Cuff Pressure increase Operator-initiated deflate Cuff Pressure Operator-initiated quick deflate/inflate Cuff Pressure	Automatic maintenance of set Cuff Pressure Operator-initiated change of set Cuff Pressure Operator-initiated time-limited Cuff Pressure increase Operator-initiated deflate Cuff Pressure Operator-initiated quick deflate/inflate Cuff Pressure	Same	
Default Cuff pressure setpoint:	25 cmH_2O	25 cmH_2O	Same	
Cuff Pressure set range:	5 cmH_2O to 50 cmH_2O	5 cmH_2O to 50 cmH_2O	Same	
Cuff Pressure setpoint and display resolution:	1 cmH_2O	1 cmH_2O	Same	
Specified Cuff Pressure accuracy:	± 1 cmH_2O	± 1 cmH_2O	Same	
Time-limited Cuff Pressure increase	Default: 5 cmH2O above set pressure for 5 min (adjustable up to 25 cmH2O above set pressure for 5 or 10 min)	Default: 5 cmH2O above set pressure for 5 min (adjustable up to 25 cmH2O above set pressure for 5 or 10 min)	Same	
Deflate-cuff Cuff Pressure	0 cmH_2O	0 cmH_2O	Same	
Quick Deflate/Inflate Cuff Pressure	Deflate Cuff Pressure to 0cmH2O and Inflate the Cuff Pressure to set Cuff Pressure target during an inspiratory cycle upon activation	Deflate Cuff Pressure to 0cmH2O and Inflate the Cuff Pressure to set Cuff Pressure target during an inspiratory cycle upon activation	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
User Interface				
Display Type	Color TFT with integrated touchscreen	Color TFT with integrated touchscreen	Same	
Displayed Units	Default: cmH20 (or hPa, mbar)	Default: cmH20 (or hPa, mbar)	Same	
Displayed values	Current cuff pressure, setpoint pressure	Current cuff pressure, setpoint pressure	Same	
Displayed information (symbols)	Cuff system leakage, cuff pressure above limit, cuff deflated, time limited hold, (!) for user shutdown denied; Tubing set not connected, deflation/ inflation in progress or complete	Cuff system leakage, cuff pressure above limit, cuff deflated, time limited hold, (!) for user shutdown denied; Tubing set not connected, deflation/ inflation in progress or complete	Same	
User Input Control Keys	Power ON / OFF Alarm silence Adjust cuff pressure UP/DOWN Time-limited hold Deflate cuff Quick Deflate/inflate cuff	Power ON / OFF Alarm silence Adjust cuff pressure UP/DOWN Time-limited hold Deflate cuff Quick Deflate/inflate cuff	Same	
Visible Alarms	Display and LED Alarm bar	Display and LED Alarm bar	Same	
Auditory Alarm Volume	50 dB(A) ± 6 dB(A), 1 m distance	50 dB(A) ± 6 dB(A), 1 m distance	Same	
High Priority Alarms	Cuff system leakage	Cuff system leakage	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Medium Priority Alarms	Pressure above set limit; Cuff Deflated; User Shutdown Denied	Pressure above set limit; Cuff Deflated; User Shutdown Denied	Same	
Additional Alarms/Alerts	Power Failure; Technical fault(s)	Power Failure; Technical fault(s)	Same	
Alarm Silence Input	Alarm silence key	Alarm silence key	Same	
Alarm Silence Indicator	Alarm silence icon, 2 minutes	Alarm silence icon, 2 minutes	Same	
Control components				
Pump type	Eccentric diaphragm pump for gases, design supports medical device applications	Eccentric diaphragm pump for gases, design supports medical device applications	Same	
Pressure sensor type	Integrated solid state pressure sensor	Integrated solid state pressure sensor	Same	
Power Specifications				
Power source: Mains	Mains AC power adapter, 100 to 240 VAC / 50 to 60 Hz; 24 VA rated, 1.25 VA typical	Mains AC power adapter, 100 to 240 VAC / 50 to 60 Hz; 24 VA rated, 1.25 VA typical	Same	
DC Power input	5V DC	5V DC	Same	
Internal Battery Type	None	None	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Mains power interruption	Internal capacitor backup	Internal capacitor backup	Same	
Mechanical Characteristics				
Housing Construction	Clamshell construction	Clamshell construction	Same	
Housing Material	ABS	ABS	Same	
Overall dimensions	Length: 22 cm Width: 8 cm Depth: 4.9 cm	Length: 22 cm Width: 8 cm Depth: 4.9 cm	Same	
Weight	500g (17.6 oz)	500g (17.6 oz)	Same	
Mounting Options	Bedside bracket	Bedside bracket	Same	
Environmental Specifications				
Operating Temperature	+5°C to 35°C	+5°C to 35°C	Same	
Operating Humidity	30% to 75%, noncondensing	30% to 75%, noncondensing	Same	
Storage Temperature	-15°C to 70°C/ 5°C to 158°F	-15°C to 70°C/ 5°C to 158°F	Same	
Storage Humidity	5% to 95%, noncondensing	5% to 95%, noncondensing	Same	
Environmental Pressure Range	70.0 kPa to 106.0 kPa (-300 m/-1,000 ft. to +3048 m/ 10,000 ft.)	70.0 kPa to 106.0 kPa (-300 m/-1,000 ft. to +3048 m/ 10,000 ft.)	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Cleaning and Disinfection Methods				
Cleaning and Disinfection Methods	Surface wipe of device reusable components per manufacturer specified wet contact times	Surface wipe of device reusable components per manufacturer specified wet contact times	Same	
Cleaning/Low-Level Disinfection Agent(s)	70% Isopropyl alcohol wipes - WEBCOL/Curity Alcohol Prep Pads or equivalent	70% Isopropyl alcohol wipes - WEBCOL/Curity Alcohol Prep Pads or equivalent	Same	
Cleaning/Intermediate Level Disinfection Agent(s)	Super Sani-Cloth® Germicidal Disposable Wipe (PDI, Inc., Woodcliff Lake, NJ, USA); Quarternary ammonium chlorides 0.55%; Isopropyl Alcohol 55.0%; 2- min. contact time; EPA Registration No. 9480-4	Super Sani-Cloth® Germicidal Disposable Wipe (PDI, Inc., Woodcliff Lake, NJ, USA); Quarternary ammonium chlorides 0.55%; Isopropyl Alcohol 55.0%; 2- min. contact time; EPA Registration No. 9480-4	Same	
Intermediate Level Disinfection Agent(s)	Sani-Cloth® Bleach Germicidal Disposable Wipe (PDI, Inc., Woodcliff Lake, NJ, USA); Sodium Hypochlorite 0.63%; %; 4- min. contact time; EPA Registration No 9480-8	Sani-Cloth® Bleach Germicidal Disposable Wipe (PDI, Inc., Woodcliff Lake, NJ, USA); Sodium Hypochlorite 0.63%; %; 4- min. contact time; EPA Registration No 9480-8	Same	
Disposable Tubing Set				
Tubing Material	DEHP free PVC	DEHP free PVC	Same	
Filter Housing Material	DEHP free PVC	DEHP free PVC	Same	
Filter Material	PTFE	PTFE	Same	
Tubing Filter Material(s)	0.2 μm bacterial filter	0.2 μm bacterial filter	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Tubing Overall Length	200 cm / 79 in	200 cm / 79 in	Same	
Disposable Tubing and Filter Packaging	Tyvek (PET/PP) peel pouch	Tyvek (PET/PP) peel pouch	Same	
Safety Compliance				
Electrical Protection Class	Class II, Type BF applied part per IEC 60601-1	Class II, Type BF applied part per IEC 60601-1	Same	
Magnetic resonance rated	MR Unsafe (device label)	MR Unsafe (device label)	Same	
Ingress Protection Rating	IP33	IP33	Same	
Standards Compliance – Device	IEC 60601-1:2005, AMD1:2012 IEC 60601-1-2:2014 IEC 62366-1:2020 IEC 60601-1-8:2006/AMD1:2012 IEC 62304:2006/AMD1:2015	IEC 60601-1:2005, AMD1:2012 IEC 60601-1-2:2014 IEC 62366-1:2020 IEC 60601-1-8:2006/AMD1:2012 IEC 62304:2006/AMD1:2015 ISO 14971 Risk Management	Same	
Non-Clinical Testing	Electrical safety testing per IEC 60601-1 Electromechanical compatibility testing per IEC 60601-1-2 Software Lifecycle evaluation to IEC 62304 Transport testing per ISTA 3A Usability evaluation per IEC 62366	Electrical safety testing per IEC 60601-1 Electromechanical compatibility testing per IEC 60601-1-2 Software Lifecycle evaluation to IEC 62304 Transport testing per ISTA 3A Usability evaluation per IEC 62366	Same	

Product/Feature	TrachFlush (Subject Device)	TrachCuff (Predicate Device)	Same, Similar or Different	Comments
Clinical Testing	Yes	N/A	Different to PD	Clinical testing results are included in this submission which demonstrates that the update of Indications for Use statement for the Subject Device does not raise any issues of safety and effectiveness

In the summary SE table above, we have demonstrated that the PD and SD are Substantial Equivalent in all Design Input Specifications for:

- Indications for Use for the "continuously measure and automatically maintain the use-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation"
- Patients, Users and Use Environment
- All Operational modes
- Technological performance including the
    - User Interface,
    - Control Components,
    - Power Specifications,
    - Mechanical Characteristics,
    - Environmental Specifications
    - Cleaning requirements,
    - Disposable Tubing Set and
    - Safety compliance

In the summary SE table above, we have also demonstrated that the SD is different to the PD, but equivalent to the Reference Device, with the addition of the Indications for Use statement of

- "assist in clearing upper airway secretions by simulating an artificial cough during mechanical ventilation"

The differences between the SD and PD in Indications for Use statement was additionally evaluated through clinical testing.

The Equivalence evaluation between the SD and the Reference Device of the artificial cough maneuver technique was evaluated through an artificial cough maneuver technological comparison description.

(b) (1) Non-Clinical testing:

As demonstrated in the previous submission **K220854**, the TrachFlush device was developed and tested to current applicable standards for medical device electrical safety and electromagnetic compatibility. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2
- Software Lifecycle evaluation to IEC 62304
- Transport testing per ISTA 3A

The device met acceptance criteria for compliance to the standards.

As demonstrated in the previous submission **K220854,** Risk management, risk and hazard analysis of the device and accessories was performed to the following standard:

- Application of risk management to medical devices per ISO 14971
- Usability evaluation per IEC 62366 for professional use

The device met risk management criteria for acceptability of residual risks.

As demonstrated in the previous submission **K220854**, the TrachFlush device embedded software was developed in accordance with FDA guidelines for MAJOR level of concern devices. The software lifecycle process was evaluated to meet:

- Medical device software lifecycle process per IEC 62304 (also assessed by independent compliance laboratory).
- Device software was verified to requirements and validated to meet the specified intended use(s).

As demonstrated in the previous submission **K220854**, the disposable accessory tubing set with filter was evaluated for biocompatibility by reference to the manufacturer's technical file.

The disposable accessory tubing set met acceptance criteria for biocompatibility.

As demonstrated in the previous submission **K220854**, the TrachFlush device was evaluated for reuse life durability for per the reprocessing methods specified in device labeling:

- Manual cleaning, low-level and intermediate-level disinfection: up to 600 cycles
- Intermediate level disinfection (bleach wipes): up to 150 cycles

The device met acceptance criteria for durability and performance after testing.

In summary, as demonstrated in the previous submission **K220854**, the TrachFlush device met acceptance criteria for conformance to applicable standards, performance, biocompatibility, cleaning and disinfection, and durability. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Testing:

Investigator driven scientific peer reviewed studies have investigated the use of the TrachFlush device to remove airway secretions, simulating an artificial cough maneuver:

- Nielsen AH, Karbing DS, Sølling CG, Winding RR, Rees SE, Dey N. Efficacy of an automated secretion removal technology at different inspiratory pressures. Respiratory Care 2023 Nov;68(11):1502-1509

- Sinnige JS, Karbing DS, Valk CMA, Schultz MJ, Rees SE, Paulus F. A prospective, longitudinal study evaluating the efficacy of an automated secretion removal technology. Respiratory Care 2024;69(8):931–936.

- Vivona L, Madotto F, Carlesso E, Florio G, Rees SE, Karbing DS, Sodi F, Zainaghi I,Rossi V, Panigada M, Zanella A. Evaluation of a new device for clearing secretions from lower airways. Respiratory Care 2025, Ahead of print

In the study of Nielsen et al. 20 intensive care patients were studied at low (21.8 ± 3.8 cmH2O) and high (25.6 ± 3.6 cmH2O) inspiratory pressure settings. Thirty-eight (86 %) of artificial cough maneuvers were considered successful, with removal of the primary symptom indicating need for tracheal suctioning and no subsequent endotracheal suctioning performed, eliminating the need for suctioning in 18 of 20 patients. No significant differences were seen in measured values of Critical-care Pain Observation Tool scores on application of the artificial cough maneuver.

In the study of Sinnige et al. 28 intensive care patients were studied at low (20.0 ± 1.5 cmH2O) inspiratory pressures during the duration of mechanical ventilation. Forty-seven (56%) of artificial cough maneuvers were considered successful, such that there were no longer secretions in the airways that needed to be removed, and that no tracheal suctioning was performed such that application of the maneuver reduced the need for ETS by more than 70 % in 13 of 24 subjects. The artificial cough maneuver was well tolerated and had side effects similar to those seen in artificial airway suctioning.

In the study of Vivona et al. 28 intensive care patients were studied at higher inspiratory pressures (35 cmH2O). Flow around the cuff due to the artificial cough maneuver was shown to mobilize tracheal secretions to the mouth in 78% of cases with adverse events consistent with artificial airway suctioning.

In summary, these peer reviewed studies have shown clinical efficacy and safety by using the TrachFlush device to remove airway secretions, simulating an artificial cough maneuver.

(3) Reference Devices technological comparison description:

An equivalence evaluation of the artificial cough maneuver technique between the RD and SD was evaluated through an artificial cough maneuver technological comparison description. AWT has identified an existing reference device cleared by the FDA (K121955) for secretion removal using the artificial cough maneuver technique.

This identified reference device is based on the maximal inspiratory-expiratory pressure delivery, aka. the MI-E functionality and/or method.

Is summary, our analysis and comparison description found that the TrachFlush artificial cough maneuver technique is equivalent to the Reference Device artificial cough maneuver technique

(3) Conclusions:

As described in (b)(1) above, the TrachFlush device is equivalent to the Predicate Device as supported by non-clinical testing.

As described in (b)(2) above, the TrachFlush device is safe and effective when removing airway secretions, simulating an artificial cough maneuver.

As described in (b)(3) above, the TrachFlush artificial cough maneuver technique is equivalent to the Reference Device artificial cough maneuver technique.

All of the above demonstrates that the TrachFlush device meets specified requirements for device safety and efficacy and is therefore substantial equivalent to the Predicate Device.