April 14, 2023

AW Technologies ApS
% Stephen Gorski
President
Imagenix, Inc.
S65W35739 Piper Road
Eagle, Wisconsin 53119

Re: K220854
Trade/Device Name: TrachCuff Cuff Controller
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: April 9, 2023
Received: April 11, 2023

Dear Stephen Gorski:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220854

Device Name
TrachCuff Cuff Controller

Indications for Use *(Describe)*

The TrachCuff Cuff Controller 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 TrachCuff Cuff Controller can be used with any mechanical ventilator.

The TrachCuff Cuff Controller 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.

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:**

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Contact Person: Mr. Adam Hansen

Position/Title: CCO

Date of Preparation: April 3, 2023

(2) **Trade Name:** TrachCuff Cuff Controller

Common/Classification Name: Cuff, Tracheal Tube, Inflatable

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

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K150893	IntelliCuff cuff controller	Hamilton Medical AG, Bonaduz, Switzerland

Reason for Submission: New Device

(4) **Description of Device:**

The TrachCuff Cuff Controller 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 TrachCuff Cuff Controller 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 TrachCuff Cuff Controller 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 TrachCuff Cuff Controller 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:

TrachCuff Cuff Controller 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 TrachCuff Cuff Controller can be used with any mechanical ventilator.

The TrachCuff Cuff Controller 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 TrachCuff Cuff Controller utilizes the same technological principles as the predicate device to continuously measure and automatically maintain the user-set cuff pressure of an ETT or TT – both devices utilize the same control methods: microcontroller-driven control of setpoint cuff pressure via air pump to cuff. Both devices utilize similar components to control the cuff pump pressure: a reciprocating air pump, solenoid air valves, and internal pressure sensors.

Comparison of Technological Features to Predicate Devices:

Product/Feature	AW Technologies TrachCuff Cuff Controller (Subject Device)	Hamilton Medical IntelliCuff (Predicate Device)	Remark
Manufacturer	AW Technologies Aps	Hamilton Medical AG	
Model Number(s)	Cuff Controller: AWT-2001 Disposable Tubing Set with Filter: TFCO02	Cuff Controller: 951001 Cuff Pressure Tube with Filter: 282016	Product range for both devices includes both cuff controller device and disposable tubing set
510(k) Number	(pending this submission)	**K150893**	
Application/Intended use:	Continuously measure and automatically maintains user-set ETT or TT cuff pressure during mechanical ventilation	Continuously measure and automatically maintains user-set ETT or TT cuff pressure during mechanical ventilation	Same
Patient Population	Adults at least 18 years who are intubated with ETT or TT	Adults, pediatrics, and neonates, who are intubated with ETT or TT	Similar – TrachCuff claims for adult ≥ 18 years are within the claims of the predicate
Environment of Use	• In the intensive care ward by Respiratory Therapist	• In the intensive care ward or in the recovery room • In the operation room during intubation narcosis • For emergency medical care or primary care • During transport within and outside of the hospital • During transfer by rescue vehicles, ship, jet, or helicopter	Similar: TrachCuff claims for professional use environments (ICU) is within the claims of the predicate IntelliCuff, which specify professional as well as emergency out of hospital transport environments.

Product/Feature	AW Technologies TrachCuff Cuff Controller (Subject Device)	Hamilton Medical IntelliCuff (Predicate Device)	Remark
Indications for use:	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. TrachCuff can be used with any mechanical ventilator. The TrachCuff 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	The IntelliCuff 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 device can be used with any mechanical ventilator, as follows: • When used with a non-Hamilton Medical ventilator, IntelliCuff adjusts the cuff pressure to values set on the device. • When used with a Hamilton Medical ventilator, IntelliCuff adjusts the cuff pressure to values set either on the device or on the ventilator, depending on configuration. The device is to be used during ventilation of adults, pediatrics, and neonates, who are intubated with ETT or TT, in the following areas: • In the intensive care ward or in the recovery room • In the operation room during intubation narcosis • For emergency medical care or primary care • During transport within and outside of the hospital • During transfer by rescue vehicles, ship, jet, or helicopter	Similar The claim for TrachCuff performing continuous cuff control is substantially identical to predicate IntelliCuff. Both devices can be used with any mechanical ventilator. TrachCuff claims for adult ≥ 18 years are within the population of IntelliCuff. TrachCuff claims for professional use environments are within the claims of the predicate IntelliCuff, which specify professional as well as emergency out of hospital transport environments.
Operation and Operating Principles			
Control Mechanism	Embedded microcontroller	Embedded microcontroller	Same

Product/Feature	AW Technologies TrachCuff Cuff Controller (Subject Device)	Hamilton Medical IntelliCuff (Predicate Device)	Remark
Operating Modes/Sequences	Automatic maintenance of set cuff pressure Operator initiated time-limited cuff pressure increase Operator initiated deflate cuff Operator initiated deflate/inflate cuff	Automatic maintenance of set cuff pressure Operator initiated time-limited cuff pressure increase Operator initiated deflate cuff Operator initiated deflate/inflate cuff	Similar
Time-limited Hold Values	Default: 5 cmH_2O above set pressure for 5 min (adjustable up to 25 cmH_2O above set pressure for 5 or 10 min)	Default: 5 cmH_2O above set pressure for 5 min (adjustable up to 25 cmH_2O above set pressure for 5 or 10 min)	Same
Cuff pressure set range:	5 cmH_2O to 50 cmH_2O	5 cmH_2O to 50 cmH_2O	Same
Cuff pressure max limit:	55 cmH_2O	55 cmH_2O	Same
Pressure setpoint and display resolution:	1 cmH_2O	1 cmH_2O	Same
Default Cuff Setpoint Pressure at power on	25 cmH_2O	25 cmH_2O (adjustable)	Similar: TrachCuff provides a fixed default setpoint at power on; IntelliCuff provides an adjustable default setpoint at power on. Default setpoint may be configured by the operator
Specified pressure accuracy:	± 1 cmH_2O	± 2 cmH_2O	Similar
Measurement principle	Solid state pressure sensor(s)	Solid state pressure sensor(s)	Same
Pump type	Eccentric diaphragm pump for gases	Eccentric diaphragm pump for gases	Same
User Interface			
Display Type	Color TFT with integrated touchscreen	Color TFT display	Similar
Displayed Units	Default: cmH_20 (hPa order option)	Default: cmH20 (or hPa, mbar)	Same
Displayed values	Current cuff pressure, setpoint pressure	Current cuff pressure, setpoint pressure	Same

Product/Feature	AW Technologies TrachCuff Cuff Controller (Subject Device)	Hamilton Medical IntelliCuff (Predicate Device)	Remark
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 deflated, time limited hold, (!) for user action denied or technical fault, battery status including low battery	Similar: TrachCuff provides additional information symbols; IntelliCuff provides battery status, TrachCuff has no internal battery
User Input Control Keys	Power ON / OFF Alarm silence Deflate cuff Time-limited hold Deflate/inflate cuff Adjust cuff pressure UP/DOWN	Power ON / OFF Alarm silence Deflate cuff Time-limited hold Lock control panel Adjust cuff pressure +/-	Similar: TrachCuff does not have screen lock but requires 3-second key press, and/or user confirmation;
Visible/Audible Alarms	✓ YES	✓ YES	Same
Power			
Power source: Mains	Mains AC power adapter, 100 to 240 VAC / 50 to 60 Hz; 24 VA rated, 1.25 VA typical; to 5 VDC	Mains AC power adapter, 100 to 240 VAC / 50 to 60 Hz; 1.25 VA typ., 3.25 VA max.; to 5 VDC	Similar for mains input
Internal Battery Type	(none)	AA (IEC-HR6) NiMH rechargeable	TrachCuff has no internal battery
Internal Capacitor Type	High-capacity capacitor to achieve 30 seconds of operation with power interruption and safe shutdown state	High-capacity capacitor to achieve 30 seconds of operation with power interruption and safe shutdown state	Same internal capacitor function for safe shutdown with power interruption (cuff pressure is maintained after shutdown)
Mains power interruption	Operation of internal capacitor provides 30 seconds for alarm and orderly shutdown to safe fallback function	Operation of internal capacitor provides 30 seconds for alarm and orderly shutdown to safe fallback function	Same
Mechanical			
Overall dimensions	Length: 22 cm (8.7 in) Width: 8 cm (3.1 in) Depth: 4.9 cm (1.9 in)	Length: 15.7 cm (6.2 in) Width: 5.5 cm (2.2 in) Depth: 3.6 cm (1.4 in)	Similar size
Weight	500g (17.7 oz)	260 g (9.2 oz)	Similar weight

Product/Feature	AW Technologies TrachCuff Cuff Controller (Subject Device)	Hamilton Medical IntelliCuff (Predicate Device)	Remark
Mounting Options	Bedside hanging bracket	Bedside hanging bracket; Rear attached rail mounting clamp	Similar
Environmental Specifications			
Operating Temperature	+5°C to 35°C	-15°C to 50°C / 5°F to 122°F	Similar – TrachCuff is specified for professional healthcare environments, IntelliCuff includes out of hospital emergency transport

As summarized above, the TrachCuff Cuff Controller utilizes equivalent technological characteristics and specifications as the cleared predicate device, including the same cuff pressure setpoint ranges and limits.

Discussion of Differences in Indications to the Predicate Device:
The subject TrachCuff device and predicate device have the following differences in their indication statements regarding use for cuff control:

- The subject device is intended to be used during ventilation of adults at least 18 years of age who are intubated with ETT or TT. The predicate device specifies adults, pediatrics, and neonates who are intubated with ETT or TT.
- The subject device is intended to be used in the intensive care ward by Respiratory Therapists. The predicate device additionally specifies use for emergency medical care; during transport within and outside of the hospital; and during transfer by rescue vehicles, ship, jet, or helicopter.
- The subject device may be used with any mechanical ventilator. The predicate device can be used with any ventilator, however when used with a Hamilton Medical ventilator, the predicate device adjusts the cuff pressure to values set either on the device or on the ventilator, depending on configuration.

The differences in the wording of the subject and predicate device indications for use are not critical to the intended use of the device as a cuff controller and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- The subject device specifies an adult (≥ 18 years) patient population within the specified patient population of the predicate device.
- The subject device claims for professional use environments are within the claims of the predicate device, which specify professional as well as emergency out of hospital transport environments.
- Both subject and predicate devices can be used with any mechanical ventilator.

Therefore, in consideration of the above, the differences identified are not critical to the intended use of the device as a cuff controller and do not affect the safety and effectiveness of the device when used as labeled.

Discussion of Technological Differences to the Predicate Device:
The subject TrachCuff device and predicate IntelliCuff device have the following technological differences:

- The specified pressure accuracy of the subject device is ± 1 cmH_2O; the specified accuracy of the predicate device is ± 2 cmH_2O. Both devices have a pressure setpoint and display resolution of 1 cmH_2O.
- The subject device does not have a screen lock but does require a 3-second key press, and/or user confirmation to change a setting. The predicate device has a screen lock which requires a long press to lock or unlock the panel.
- The subject device does not have an internal battery and is specified for use in professional healthcare environments. The predicate device does have an internal battery and is specified for use in professional as well as out of hospital transport environments. Both devices have an internal high-capacity capacitor which provides 30 seconds of operation in the event of power loss and allows the device to achieve a safe shutdown state with cuff pressure maintained.

The technological differences in the subject and predicate device are not critical to the intended use of the device as a cuff controller and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- The subject device specified pressure accuracy is slightly more accurate than the predicate device accuracy. Subject device pressure accuracy has been confirmed by testing.
- The subject device screen functionality includes a requirement for an intentional long press or user confirmation for any setting to be changed, which achieves a similar functionality as a screen lock.
- The lack of an internal battery does not limit the use of the subject device for use in professional healthcare environments. In the event of mains power interruption, the subject device is able to achieve a safe shutdown state with cuff pressure maintained, which is equivalent to the predicate device safe shutdown, as confirmed by testing.

Evidence of safety and effectiveness in support of substantial equivalence were obtained from design verification and validation testing. The differences identified above were found not to affect performance or safety through design verification activities that demonstrated conformance to specifications and performance requirements, as well as applicable medical device performance standards and other non-clinical testing.

(b) (1) Non-Clinical Tests Submitted:

The TrachCuff Cuff Controller was laboratory 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.

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

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

Device and accessories usability was evaluated to the following:

- Usability evaluation per IEC 62366 for professional use
- Summative usability testing of the device in a representative population of USA clinical users, including critical use functions and user comprehension of key elements of the instructions for use.

The device met evaluation criteria for usability in the user group.

The TrachCuff 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).

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.

The TrachCuff Cuff Controller 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, the TrachCuff Cuff Controller met acceptance criteria for conformance to applicable standards, performance, biocompatibility, cleaning and disinfection, usability, and durability. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted:

(none)

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the TrachCuff Cuff Controller is equivalent to the predicate cuff controller as supported by compliance, laboratory, and biocompatibility evaluation(s).

The results of all tests demonstrate that the TrachCuff Cuff Controller meets specified requirements for device safety and substantial equivalence to the referenced predicate devices.