August 12, 2025

Idmed
Perrine Moelle
Quality & Regulatory Affairs Director
3 rue John Maynard Keynes
Marseille, 13013
France

Re: K243562
Trade/Device Name: CuffGuard
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: July 7, 2025
Received: July 7, 2025

Dear Perrine Moelle:

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,

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243562

Device Name

CuffGuard

Indications for Use *(Describe)*

The CuffGuard is an endotracheal tube cuff controller designed to continuously monitor and maintain user-defined endotracheal tube cuff pressure for patients (adults and pediatrics) who require mechanical ventilation and who are intubated with endotracheal tube including cuff in the ICU, OR and for intra-hospital transport.

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.

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510 (k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

Submitter: IDMED
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Establishment Registration Number: N° DUNS 260233256

Contact person: Perrine MOLLE
Quality & Regulatory Affairs Director
E-mail : p.molle@idmed.fr

Date Summary Prepared: 2025/07/03

2. Device

Trade Name:	CuffGuard (references CG-MU_ID and CG-MU_DR)
Common/Usual Name:	Tracheal tube cuff Pressure Controller
Regulation Name:	Inflatable tracheal tube cuff
Classification Regulation:	21 CFR 868.5750
Product Code:	BSK
Regulatory Class:	Class II

3. Predicate device

Predicate Device: Intellicuff, manufactured by Hamilton Medical, K150893

1.1. Device description

The CuffGuard is an endotracheal tube cuff controller designed to continuously monitor and maintain user-defined endotracheal tube cuff pressure for patients (adults and pediatrics) who require mechanical

ventilation and who are intubated with endotracheal tube including cuff in the ICU, OR and for intra-hospital transport.

It is used by health professionals (doctor or nurse) specifically trained in this tool.

The CuffGuard has a pressure sensor and software that can monitor and automatically adjust the cuff pressure.

The accessories associated include:

- Connection tube with filter
- Power supply
- Micro USB connection cable
- Fixation clamp and its tilt block)

At a high level, the comparison of the subject and predicate devices is based on the following table:

Features	**CuffGuard**	**Intellicuff**
Product code	BSK	BSK
Regulation number	868.5750	868.5750
Class	II	II
Indication for use		
Intended use	The CuffGuard is an endotracheal tube cuff controller designed to continuously monitor and maintain user-defined endotracheal tube cuff pressure for patients (adults and pediatrics) who require mechanical ventilation and who are intubated with endotracheal tube including cuff.	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
Environment of use	In a professional health care setting such as hospital or health care facility: in an Intensive Care Unit, an Operating Room and during intra-hospital transportation.	Intensive care units, operating rooms, and during interhospital transport: - 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

Features	CuffGuard	Intellicuff
Product code	BSK	BSK
Regulation number	868.5750	868.5750
Class	II	II
User	Health professional (doctor or nurse) specifically trained in this tool	Trained and qualified professionals under the supervision of a doctor and within the limits of the technical specifications indicated
Patient population	Adult and pediatric	Adults, pediatrics, and neonates, who are intubated with ETT or TT
Contraindication	None known. Note that any contraindication to the use of the endotracheal tube will result in a contraindication to the use of the CuffGuard	None identified in the IFU
Principle of operation and performances		
Principe of operation	Software-controlled pressure supervision and automatic pressure adjustment Pressure sensor Use of ambient / room air	Software-controlled pressure supervision and automatic pressure adjustment Pressure sensor Use of ambient / room air
Type of control	Automatic	Automatic
Pressure range	5 – 40 cmH2O	5 – 50 cmH2O
Accuracy of the control	+/- 2cmH2O	+/- 2cmH2O
Adjustement of accuracy	+/- 1cmH2O	+/- 1cmH2O
Display of accuracy	+/- 1cmH2O	+/- 1cmH2O
Technology characteristics		
Leak alarm	Yes	Yes
Pressure alarm	Yes	Yes
Stop sound alarm	Yes	Yes
Audible alarm	Yes	Yes
Visual alarm	Yes	Yes
Deflate Cuff	Yes	Yes
Inflate Cuff	Yes	Yes
Time-limited hold	Yes	Yes
Choice of unit	Yes	Yes
Energy	Battery and AC power supply	Battery and AC power supply
Portable device	Yes	Yes

Features	CuffGuard	Intellicuff
Product code	BSK	BSK
Regulation number	868.5750	868.5750
Class	II	II
General safety	Conpliant to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8	Conpliant to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-12
Biological characteritics		
Patient contact material	NA, no patient contact	NA, no patient contact

1.2. Indications for use

The CuffGuard is an endotracheal tube cuff controller designed to continuously monitor and maintain user-defined endotracheal tube cuff pressure for patients (adults and pediatrics) who require mechanical ventilation and who are intubated with endotracheal tube including cuff in the ICU, OR and for intra-hospital transport.

The following differences exist between subject and predicate device:

- The subject device is not indicated to be used on tracheostomy tube (TT)
- The subject device is not indicated to be used on neonate population of patient
- The subject device is not indicated to be used during transfer by rescue vehicles, ship, jet or helicopter

However, these differences do not raise questions of safety and effectiveness, because:

- the indication not applicable for the subject device (Tracheostomy tube),
- the population not applicable for the subject device (neonate),
- the environment of use not applicable for the subject device (transfer by rescue vehicles, ship, jet, or helicopter),

are not considered for the comparison.

The subject device and its predicate device are both used in the same clinical conditions or purposes (adult or pediatric patients requiring mechanical ventilation for whom the cuff pressure of an endotracheal tube (ETT) is monitored) and are used by the same kind of users (trained medical professional). They have the same principle of operation, using a pressure sensor and air pump).

4. Comparison of technological characteristics with the predicate device

The technological principle of the subject device is to maintain and automatically adjust thanks to embedded software, the cuff pressure of intubating tubes using a pressure sensor and a pump.

The following technological difference exists between subject device and its predicate device:

- The pressure range of the subject device is not as wide as its predicate device

However, this difference is supported by performance data (Software verification or safety test reports). Furthermore, this difference does not raise different questions of safety and effectiveness and does not negatively affect the clinical performances for the following reason:

- Difference of pressure range has been evaluated on the SW verification and validation. Furthermore, this difference is not clinically significant as the use of pressure range until 40 cm H2O appears as a realistic physiological limit and as a common clinical practice used as shown on various publications.

5. Performance data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CuffGuard device. The system complies with the IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-8 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The documentation level for CuffGuard software is enhanced.

Animal and Clinical Studies

No animal or clinical testing was required to demonstrate the substantial equivalence of this device to its predicate, nor its safety and effectiveness.

6. Conclusions

Based on its intended use, design principles, and technological characteristics, the CuffGuard device was found to be as safe, as effective, and performs comparably to the predicate device.

The technological differences identified do not raise new questions of safety and effectiveness as the non-clinical and clinical literature data support the safety of the device and the hardware and software verification and validation demonstrate that the CuffGuard device should perform as intended in the specified use conditions.