March 7, 2025

Shanghai Longmann Tech Co., Ltd.
℅ Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K242642
Trade/Device Name: CuffTrek
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: February 12, 2025
Received: February 12, 2025

Dear Charles Mack:

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
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)*

K242642

Device Name

CuffTrek

Indications for Use *(Describe)*

The CuffTrek is intended to measure and regulate the intracuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use from pediatric to adult, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated. It is for disposable single patient use.

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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"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 K

Preparation Date:	September 2, 2024
Manufacturer's Name and Address:	Shanghai Longmann Tech Co., Ltd. Room 2106, No.3, Lane791, Lingling Road Shanghai, China 200030 Tel. +86-139-01718104
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	CuffTrek™
Common Name(s):	Inflatable tracheal tube cuff
Regulation Name(s):	cuff, tracheal tube, inflatable
Regulation Number(s):	21CFR868.5750
Primary Product Code: Subsequent Product Codes:	BSK
Device Class:	Class II
Predicate Device: Trade Name: Common Name: Regulation Number(s): Product Code:	K122721 AG Cuffill Inflatable tracheal tube cuff 21CFR868.5750 BSK
Reference Device: Trade Name: Common Name: Regulation Number(s): Product Code:	K192611 Cuffix Inflatable tracheal tube cuff 21CFR868.5750 BSK

Device Description:

The device is a battery-operated cuff pressure-controlling device intended to be used with ventilation tubes (ETT, Tracheostomy, LMA). It is a single patient-use, non-sterile device designed to be used continuously for up to 7 days. The device is connected to the pilot balloon of airways with inflatable air-filled cuffs via the device's extension line. The operating range of the device is 0-99 cmH2O. The device body houses the active pressure monitoring mechanism, which displays the cuff pressure on the digital screen. An indicator light provides an additional visual aid to indicate whether the cuff pressure is at the correct pressure or if the pressure is out of the set range of 20-30 cmH2O (red).

Principles of Operation:

The device is a new single-use medical device whose purpose is to continuously measure the pressure inside an endotracheal tube balloon while in use so that it remains within safe limits. The inflation status of the balloon is displayed on a digital screen at a glance from a distance.

Indications for Use

The CuffTrekTM is intended to measure and regulate the intracuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use from pediatric to adult, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated. It is for disposable single patient use.

Characteristics	Subject device	Predicate device	Reference device	Discussion
Device Name	CuffTrek™	AG Cuffill	Cuffix	-
510(K) Number	Pending	K122721	K192611	-
Regulation Name	Inflatable Tracheal Tube Cuff	Inflatable Tracheal Tube Cuff	Inflatable Tracheal Tube Cuff	-
Common name	Cuff Pressure Regulator	Cuff Pressure Regulator	Cuff Pressure Regulator	-
CFR	868.5750	868.5750	868.5750	-
Product code	BSK	BSK	BSK	-
Indication for use	The CuffTrek™ is intended to measure and regulate the intracuff pressure of Endotracheal tubes, Tracheotomy tubes, and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single-patient use from pediatric to adult, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated. It is for disposable single-patient use.	The Hospitech AG Cuffill is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheotomy tubes, and Laryngeal Masks Airways (LMAs) (supraglottic airways). The Hospitech AG Cuffill is used under medical supervision in hospitals, pre-hospital(EMS), extended care facilities, and outpatient clinics, where a patient may be intubated.	The Cuffix is intended to measure and regulate, through passive control, the intracuff pressure of Endotracheal tubes, Tracheotomy tubes, and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single-patient use under medical supervision in hospitals, pre-hospital (EMS), extended care facilities, or outpatient clinics, where a patient may be intubated.	*Identical to Predicate Note 1*
Prescription Use	Prescription	Prescription	Prescription	*Identical*
Types of airway to which it can be used	Endotracheal tubes Tracheotomy tubes Laryngeal Masks Airways (LMAs)(supraglottic airways)	Endotracheal tubes Tracheotomy tubes Laryngeal Masks Airways (LMAs) (supraglottic airways)	Endotracheal tubes Tracheotomy tubes Laryngeal Masks Airways (LMAs) (supraglottic airways)	*Identical*
Cuff pressure range	20-30 cmH_2O	20-30 cmH_2O	20-30 cmH_2O	*Identical*

Characteristics	Subject device	Predicate device	Reference device	*Discuss*
Operating range	0-99 cmH_2O	0-99 cmH_2O	0-99 cmH_2O	*Identica*
Pressure display	Digital screen	Digital screen	The pointer indicates the range of pressure values	*Identica*
Alarm when pressure is out of range	Yes - blinking red light	No	Yes - blinking red light	*Note 2*
Continuous monitoring of cuff pressure	Yes	No	Yes	*Note 2*
Accuracy	±2 cmH_2O	±2 cmH_2O	±3 cmH_2O	*Identica to Predicat*
Inflation by syringe	Yes	Yes	Yes	*Identica*
Connection to pilot balloon using luer connector	Yes	Yes	Yes	*Identica*
Operation time	up to 7 days	*100 operations (measurements)*	Up to 2 weeks	*Note 3*
Patient contact	Does not come in direct or indirect contact with the patient or the user	Does not come in direct or indirect contact with the patient or the user	Does not come in direct or indirect contact with the patient or the user	*Identica*
Provided sterile	No	No	No	*Identica*
Type of control	Active control: syringe inflation by user	Active control: syringe inflation by user	Active control: syringe inflation by the user. Passive control: elastic inner balloon	*Identica to Predicat Note 4*

Discussion:

Note 1:

The subject device's IFU is identical to the predicate and specifies the populations additionally. The reference device has an additional passive control feature that is not included by the subject device. The subject device is disposable for single-patient use only and cannot be reused if disconnected from the pilot balloon of the ventilation tube.

Note 2:

The predicate device is unavailable for continuous monitoring and has no alarm function. The subject device is available for continuous monitoring and has an additional alarm function for continuous cuff pressure monitoring, the same as the reference device. It will be alarmed by a red light when pressure is out of the preferred range of 20-30 cmH_2O, the same as the reference device. The performance test verifies it, and the difference doesn't raise new questions on the safety and effectiveness of the subject device.

Note 3:

The operation time of the subject device is different from that of the predicate devices but within the scope of reference devices. The performance test verified this. The difference doesn't raise new questions about the safety and effectiveness of the subject device.

Note 4:

The subject device only has active control by syringe, the same as the predicate and reference device. The reference device has additional passive control by an elastic inner balloon to maintain the pressure but still needs to use active control by syringe to regulate/adjust the pressure when alarm the pressure is out of the preferred range

Performance Testing

To establish substantial equivalence to the identified predicate devices, we compared the tests below on the subject devices, CuffTrek™, and the testing results provided evidence that the devices comply with the requirements and are substantially equivalent to the predicate device.

Non-Clinical Study:

Non-clinical tests were conducted to verify that the proposed devices met all design specifications and were Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed devices comply with the following standards:

Safety and EMC

To verify the basic safety and essential performance of the CuffTrek™, we performed the below test:

- *ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- *IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

Performance Data:

- *ISO 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications*
- *ISO 80369-20 First edition 2015-05-15 Small-bore connectors for liquids and gases in healthcare applications-Part 20: Common test methods*

Test conducted:

- *Fluid leakage*
- *Sub-atmospheric pressure air leakage*
- *Stress cracking*
- *Resistance to separation from axial load*
- *Resistance to separation from unscrewing*
- *Resistance to overriding*
- *Response time*
- *Pressure accuracy test*
- *Repeatability pressure accuracy test*
- *Pressure accuracy test exposure to cold and hot temperature*
- *Inflation and deflation functions*
- *Operation time*
- *Battery Shelf Life*
- *Comparative Testing (to CuffTrek™ and the predicate AG Cuffill)*

Biocompatibility

N/A.

The subject device does not come in direct or indirect contact with the patient or the user, the same as the predicate device.

Clinical Study:

Not applicable.

Conclusion:

Based on the above-listed tests, the CuffTrek™ fully complies with the applicable standards requirement and does not raise new safety issues and effectiveness of the devices, demonstrating that it is identical to the predicate device in safety and effectiveness properties.

END