June 16, 2026

Hunan Ruijiong Biotech Co., Ltd.
Zen Koo
FDA Compliance Officer
Floor 2 Block 6 of Innovation and Incubator Center
35 Dongfeng Road, Xiangtan Economic Developing-area
Xiangtan, Hunan 411100
China

Re: K253001
Trade/Device Name: KT Airway Clearance Device II (KT-3); KT Airway Clearance Device II (KT-5)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: May 9, 2026
Received: May 11, 2026

Dear Zen Koo:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.06.16 11:14:59 -04'00'

For

Rachana Visaria
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)*
K253001

Device Name
KT Airway Clearance Device II (KT-3); KT Airway Clearance Device II (KT-5)

Indications for Use *(Describe)*
The KT Airway Clearance Device II is designed for the use on patients unable to cough or clear secretions effectively by applying a positive pressure to the airway, then rapidly shifting to a negative pressure, or providing high frequency oscillatory vibrations.
The device may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.
For use in hospital, institutional setting.
For use on adult or pediatric patients 3 years of age and older who have difficulty with secretion clearance and/or inability to cough.

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

510(k) #: K253001

Prepared on 6-15-2026

Contact Details

Applicant Name: HUNAN RUIJIONG BIOTECH CO., LTD.

Applicant Address: Floor 2 Block 6 of innovation and incubator center 35 Dongfeng Road, Xiangtan Economic Developing-area xiangtan hunan 411100 China

Applicant Contact Telephone: 203-5302097

Applicant Contact: Ms Zen Koo

Applicant Contact Email: rj-zc@outlook.com

Device Name

Device Trade Name: KT Airway Clearance Device II (KT-3); KT Airway Clearance Device II (KT-5)

Common Name: Noncontinuous ventilator (IPPB)

Classification Name: Device, Positive Pressure Breathing, Intermittent

Regulation Number: 868.5905 Class II

Product Code(s): NHJ

Primary Predicate Device(s)

Dima Italia Srl PEGASO A-COUGH PERC (K140598)

Reference Device(s)

Breas Medical AB Clearo (K242438)

Device Description Summary

The KT Airway Clearance Device II is an active, non-implantable, and non-sterile medical device intended to provide Mechanical Insufflation-Exsufflation (MI-E) therapy for patients with impaired cough function. It is designed to assist in the clearance of retained bronchopulmonary secretions by simulating a natural cough.

The device operates by applying a positive air pressure to the patient's airway, followed by a rapid

transition to a negative pressure, thereby stimulating a cough-like effect. At the end of the pressure cycle, the airway is left at zero pressure for a user-defined pause duration.

The device consists of a blower that generates airflow and pressure, and a mechanical valve that controls the direction and intensity of air pressure delivered to the patient. The blower draws ambient air and modulates it to produce either positive or negative pressure. Pressure levels are regulated by an electronic sensor, and the blower operates at a constant speed. Internal memory stores predefined pressure generation parameters, and the system does not use a closed-loop control mechanism.,

The device is designed for non-sterile, external use, and is intended for use with appropriate patient interfaces (e.g., mask or mouthpiece). It offers multiple operating modes, including:

Cough Assistant (Manual and Automatic Mode): In Manual Mode, the clinician initiates each insufflation and exsufflation cycle, whereas in Automatic Mode the device automatically delivers pre-programmed therapy cycles based on user-selected pressure and timing parameters.

Percussor: Percussor mode superimposes high-frequency oscillatory pressure pulses onto the therapy cycle to promote secretion mobilization and airway clearance. The oscillation frequency and inspiratory-to-expiratory timing ratio can be adjusted by the user to provide customized airway-clearance therapy.

VDCP Percussor: Variable Duty Cycle Percussion (VDCP) mode is an oscillatory therapy mode that allows adjustment of the inspiratory-to-expiratory duty cycle of the percussion waveform. By varying the relative duration of inspiratory and expiratory oscillatory phases, VDCP provides additional flexibility in oscillatory pressure delivery while maintaining the same fundamental airway-clearance mechanism as conventional percussion therapy.

The device does not incorporate any invasive components and is intended for use under the supervision of a healthcare professional.

The device has 2 models: KT-3 and KT-5, they are only different in screen display size, KT-3 with 10 inch screen and KT-5 with 8 inch screen.

Intended Use/Indications for Use

The KT Airway Clearance Device II is designed for the use on patients unable to cough or clear secretions effectively by applying a positive pressure to the airway, then rapidly shifting to a negative pressure, or providing high frequency oscillatory vibrations.

The device may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.

For use in hospital, institutional setting.

For use on adult or pediatric patients 3 years of age and older who have difficulty with secretion clearance and/or inability to cough.

Technological Comparison

The KT Airway Clearance Device II is substantially equivalent to the following predicate devices:

PEGASO A-COUGH PERC (K140598) by Dima Italia Srl

The Breas Medical AB Clearo (K242438) device is referenced only to establish the safety acceptability of the oscillatory function used in the Automatic and Manual modes of the subject device.

The subject device has the same intended use, employs comparable technology, and operates via identical physiological mechanisms for airway clearance. While there are differences in use environment (not for home use), data transfer methods (SD card only), and specific parameter ranges or mode names, these are not clinically significant and do not affect the safety or effectiveness of the device.

All technical parameters - including pressure ranges, timing, frequency, and patient interface options - fall within the range of those used in predicate devices. The additional VDCP mode is a modified form of percussive therapy and does not introduce new risks.

The KT device meets the same regulatory standards for electrical safety, mechanical safety, biocompatibility and is manufactured under a quality system compliant with ISO 13485.

The Ruijiong KT Airway Clearance Device II is not materially different from legally marketed predicate devices in ways that would affect its risk profile or clinical functionality.

The KT Airway Clearance Device II is substantially equivalent to the referenced predicate devices in terms of:

Technical Characteristic	Ruijiong Biotech KT Airway Clearance Device II Subject device	Dima Italia Srl PEGASO A-COUGH PERC (Predicate device – K140598)	Discussion of Differences

Indications for Use	The KT Airway Clearance Device II is designed for the use on patients unable to cough or clear secretions effectively by applying a positive pressure to the airway, then rapidly shifting to a negative pressure, or providing high frequency oscillatory vibrations. The device may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting. For use on adult or pediatric patients 3 years of age and older who have difficulty with secretion clearance and/or inability to cough.	The PEGASO COUGH is designed for the use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or home use given adequate training. For use on adult patients and pediatric patients 3 years old and up.	Similar Remark 1
Delivery Type	Non-invasive or invasive	Non-invasive or invasive	Same
Patient Population	Pediatric through adult patients	Pediatric through adult patients	Same
Use Environment	Institutions, hospital.	Home, institutions, hospital.	Similar Remark 1
Patient Circuit Types	Patient circuit with bacterial Filter	Patient circuit with bacterial Filter	Same
Patient Interfaces	facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.	facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.	Same
Gas Delivery System and Air Source	Blower and valve, Ambient air	Blower and valve, Ambient air	Same
Power source	Mains Non-detachable lithium-ion internal battery	Mains Non-detachable lithium-ion internal battery	Same
SpO2 and Pulse Rate Monitoring	Ability to connect optional SpO2 sensor accessories	Ability to connect optional SpO2 sensor accessories	Same
Modes	Auto Mode Manual Mode Percussor Mode VDCP Mode	Auto Mode Manual Mode Percussor Mode	Similar Remark 2
Pressure	Inhale: 0 to 70 cmH2O Exhale: 0 to -70 cmH2O	Inhale: 0 to 70 cmH2O Exhale: 0 to -70 cmH2O	Similar Remark 3

Time	Inhale:0.5 to 5.0 sec Exhale: 0.1 to 1.0 sec	Inhale:0.1 to 9.9 sec Exhale:0.1 to 9.9 sec	Similar Remark 4
Pause Time	0.2 to 9.9 sec between Insufflation Breaths Only available in Auto Mode	0.1 to 9.9 sec between Insufflation Breaths Only available in Auto Mode	Similar Remark 4
Inhale Flow Level	Low,Medium,High,Peak Available in Auto and Manual Mode	Low,Medium,High, Peak Available in Auto and Manual Mode	Similar Remark 5
Physiological Alarms	None	None	Same
Technical Alarms	• Overpressure alarm • Over-temperature alarm • Pressure sensor failure alarm • Flow sensor failure alarm • SpO_2 module communication failure alarm • I^2C communication failure alarm • EEPROM memory read/write failure alarm • Stepper motor zeroing/positioning failure alarm • Fan/blower malfunction alarm • Battery or power supply fault alarm (if applicable) • System self-test/startup diagnostic failure alarm • Internal hardware fault alarm • Therapy interruption or abnormal therapy delivery alarm • Sensor communication loss alarm	Not publicly available	Similar Remark 6
Frequency	Percussion: 50 to 550 bpm Oscillations: 3.3 Hz	Percussion: 50 to 600 bpm	Similar Remark 7
Remote Data Access	SD Card	RS232/USB adapter	Similar Remark 8

Remark

Remark 1 The Ruijiong KT device is intended for hospital and institutional use only, which represents a narrowing of the intended environment compared to the predicates. This is not a change in the device's function, technology, or patient risk profile.
Conclusion: this is a narrowed scope of use, without altering the core functionality or safety profile.

Remark 2 RUIJIONG's Auto Mode, Manual Mode, Percussor Mode are same with Dima's, and

RUIJIONG's VDCP (Variable Duty Cycle Percussor) mode is a specific type of Percussor, it refers to the situation where the duty cycle during the inhalation time is different from that during the exhalation time. That is, the ratio of the duration of positive pressure to zero pressure during inhalation time equals the ratio of the duration of zero pressure to positive pressure during exhalation time.

It does not introduce new mechanisms or patient risks and is functionally within the scope of existing percussive therapy modes used in predicate devices.

Conclusion: the mode of RUIJIONG's device falls within the range of predicate devices, without altering the core functionality or safety profile

Remark 3 RUIJIONG's pressures are same with Dima's

Conclusion: The parameter range of RUIJIONG's device falls within the range of predicate devices, without altering the core functionality or safety profile

Remark 4 The Pegaso's allows operator control from 0.1 to 9.9 seconds, providing a wider range as needed by patients. RUIJIONG controls them as follows: Inhale: 0.5 to 5.0 seconds, Exhale: 0.1 to 1.0 seconds, Pause: 0.2 to 9.9 seconds.

In terms of cough assistance therapy, it simulates the patient's cough. To expel secretions from the patient's airway, a "slow inhalation, rapid exhalation" breathing pattern is required. A longer inhalation time can reduce the average inhalation flow rate, achieving the purpose of slow inhalation. A shorter exhalation time allows the patient to exhale at a relatively high flow rate, expelling airway secretions.

Setting too short an inhalation time is not conducive to achieving the purpose of slow inhalation; too long an exhalation time also keeps the lungs under continuous negative pressure. A shorter exhalation time can still achieve a high flow rate at the beginning of exhalation. The pause time, when the airway pressure is zero, allows the patient to breathe freely.

Conclusion: The parameter range of RUIJIONG's device falls within the range of predicate devices, without altering the core functionality or safety profile.

Remark 5 The duration of pressure increase varies depending on the flow level. The pressure gradually increases from zero to the set pressure. Each flow level has its own specific duration of pressure increase.

Conclusion: The parameter range of RUIJIONG's device falls within the range of predicate devices, without altering the core functionality or safety profile.

Remark 6 Reference device K242438, Breas Medical Clearo, includes the following technical alarms: High Pressure Alarm, Power Source Change Alarm, Power Fail Alarm, Pressure Measurement Fault Alarm, Pressure Sensor Fault Alarm, Batter Exhausted Alarm, SpO2 Sensor Disconnected Alarm, Battery Power Alarm. Technical alarms are comparable to the subject device.

Remark 7 Percussion frequency: RUIJIONG's Percussion frequency is 50 to 550 bpm, it is within the rage of Dima's (50 to 600 bpm).

Oscillation: The Breas Medical AB Clearo (K242438) device is referenced only to establish the safety acceptability of the oscillatory function used in the Automatic and Manual modes of the subject device. The RUIJIONG device's oscillation frequency (3.3 Hz) lies within the cleared operating range of the Clearo device (1-20 Hz), a range supported by clinical data and labeling of the legally marketed device.

Conclusion: The parameter range of RUIJIONG's device falls within the range of predicate

devices, without altering the core functionality or safety profile.

Remark 8 RUIJIONG's KT Device uses an SD card to transmits the data.
The Ruijiong KT Device provides data storage via SD card for therapy session recording. While it does not support USB or RS232 interfaces, this does not impact core safety or efficacy, and the recorded data remains accessible for clinical review.
Conclusion: This design choice reflects a simplified feature set, not a reduction in therapeutic capability, without altering the core functionality or safety profile.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following non-clinical bench tests were conducted on final, finished production devices to demonstrate substantial equivalence of the KT Airway Clearance Device II to the predicate device PEGASO A-COUGH PERC (K140598):

Standards

- Electrical Safety: IEC 60601-1 (2005/AMD2:2021) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- Electromagnetic compatibility: IEC 60601-1-2 (2014/A1:2020) Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances-Requirements and tests.

- Alarms systems: IEC 60601-1-8:2020 Edition 2.2 Consolidated Version, Medical electrical equipment-Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- Battery Safety: IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

- Packaging and Transportation:
  Validation performed per ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.

Biocompatibility:

Tissue Contacting Materials:

Component	**Contact Type**	**Contact Duration**
Gas Pathway	Indirect, External Communicating Device, Tissue/Bone/Dentin	(>30 days)
External Surface of Main Unit and Accessories	Direct, Surface Device, Intact Skin	(>30 days)
Patient Circuit and Bacterial Filter	Indirect, External Communicating Device: Tissue/Bone/Dentin	(>30 days)

- Biological evaluation was conducted according to FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a

risk management process" issued on September 8, 2023.

- ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 18562-1:2024, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 18562-2:2024, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 2: Tests for Emissions of Particulate Matter
- ISO 18562-3:2024, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 3: Tests for Emissions of Volatile Organic Compounds (VOCs)
- ISO 18562-4:2024, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 4: Tests for Leachables in Condensate

Software

- Software information included Verification and Validation testing per FDA Guidance, “Content of Premarket Submissions for Device Software Functions Guidance. System-level validation against user requirement specifications were performed according to plans and protocols and have met all acceptance criteria.

Cybersecurity

- Security Risk Management is employed in conformance to FDA's Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. This is in parallel to safety risk management per ISO 14971.

Human Factors

- Human factors and usability engineering activities were performed in accordance with IEC 62366-1:2015/AMD1:2020, ISO 14971:2019, and FDA's guidance document, *Applying Human Factors and Usability Engineering to Medical Devices* (February 2016).

Cleaning:

- Cleaning Validation was performed according to FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Issued on: March 17, 2015, updated on June 9, 2017.

Device Performance and Function:

- Core performance parameters (pressure, flow, timing) tested against product specifications based on predicate device performance
- Waveform comparison testing was performed against the predicate Pegaso Cough. Results confirm that the KT Airway Clearance Device II and the predicate have comparable waveforms across the various modes for mechanical insufflation-exsufflation therapy.
- Device lifetime evaluated using engineering analysis (Finite Element Analysis). Confirmed reliability over intended service life all acceptance criteria.
- Cybersecurity is employed in conformance to FDA's Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance. This is in parallel to safety risk management per ISO 14971 :2019 – Medical devices — Application of risk management to medical devices.

Conclusions

The results of all nonclinical testing confirm that the KT Airway Clearance Device II meets or exceeds all applicable safety standards and demonstrates performance equivalent to the predicate device PEGASO A-COUGH PERC (K140598). The KT Airway Clearance Device II has the same intended use as the predicate device, with a narrowed use environment (hospital and institutional settings only) that does not alter the core functionality, technological basis, or patient risk profile. Therefore, the KT Airway Clearance Device II is substantially equivalent to the legally marketed predicate device PEGASO A-COUGH PERC (K140598), with the Breas Medical AB Clearo (K242438) serving as a reference device to establish the safety and substantial equivalence of the oscillatory function.