March 12, 2023

Hsiner Co., Ltd.
% Yvonne Chen
Regulatory Affairs Consultant
Voler Biotech Consulting CO., Ltd
6F.-17, No. 14, Lane 609, Section 5, Chongxin Road, Sanchong District
New Taipei City, 241407
Taiwan

Re: K251888
Trade/Device Name: VPAP Pediatric Face Mask
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: February 11, 2026
Received: February 11, 2026

Dear Yvonne Chen:

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), 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 Medical Device File (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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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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.

510(k) Number *(if known)*
K251888

Device Name
VPAP Pediatric Face Mask

Indications for Use *(Describe)*
The mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency.
The mask is for single patient use in the hospital/institutional environment only.
The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.

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

1. Submission Information

Submitter: HSINER CO., LTD
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Date of preparation: 2026/03/11

2. Device Name and Classification

Product Name:	VPAP Pediatric Face Mask
Classification Name:	Continuous ventilator
Common or Usual Name:	Face mask
Regulation Number:	868.5895
Product Code:	CBK

3. 1 Predicate Device(s)

Product Name:	AF531 SE Full Face Mask
Common or Usual Name:	Face mask
Regulation Number:	868.5895
Product Code:	CBK
510(k) Number	K101129

2 Reference Device(s)

Product Name:	Hsiner NIPPV Masks
Common or Usual Name:	Face mask
Regulation Number:	868.5895
Product Code:	CBK
510(k) Number	K102120

4. Device Description

The VPAP Pediatric Face Mask is designed for pediatric patients in hospital and institutional settings, serving as an interface for Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure (BiPAP) therapy. Available in two sizes to accommodate varying facial dimensions of pediatric patients, these

masks ensure a comfortable and secure fit. The VPAP Pediatric Face Mask is intended for single-patient, supporting consistent and reliable noninvasive ventilation.

5. Indications for Use

The mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency.

The mask is for single patient use in the hospital/institutional environment only.

The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.

6. Comparison to the Predicate Device

	Subject Device – VPAP Pediatric Face Mask	**1 Predicate Device (K101129) –AF531 SE Full Face Mask**	**Brief comparison**
Class	II	II	Substantially equivalent
Regulation No	21 CFR 868.5895	21 CFR 868.5895	Substantially equivalent
Product Code	CBK	CBK	Substantially equivalent
Patient Population	Patients 7 years or older (>40 lbs/20 kg)	Patients 7 years or older (>40 lbs/20 kg)	Substantially equivalent
Indications for Use	The mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory	The small size AF531 SE Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for	Substantially equivalent

	failure of respiratory insufficiency. The mask is for single patient use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.	treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/ institutional environment only. The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.	
Sterility	Non-sterile	Non-sterile	Substantially equivalent
Intended Environment for Use	Hospital/institutional environment	Hospital/institutional environment	Substantially equivalent
Duration of Use	Single patient	Single patient	Substantially equivalent
Mask Sizes	L-Model 11316 XL-Model 11317	Small Model	Different
Operating Pressure Range	5-20 cmH_2O	4-20 cmH_2O	Different
Technical specification			
Interface Connections	22mm/15mm ISO 5356-1:2015	22mm/15mm ISO 5356-1:2015	Substantially equivalent
Dead Space (ml)	L：116 XL：148	S：278	Different
Resistance to Flow (cmH_2O)	L：0.7@50 l/min; 2.9@100 l/min XL：0.7@50 l/min; 2.9@100 l/min	0.4@50 l/min; 1.2@100 l/min	Different
Material	Mask Frame: PC Mask Cushion :Silicone Tubing: Silicone Headgear and ring: SBR, Nylon and TPU	Mask Frame: PC Mask Cushion :Silicone Headgear and ring: SBR, Nylon and TPU	Similar
Patient Contact Material	Silicone, TPU, SBR, Nylon	Silicone, TPU, SBR, Nylon	Substantially equivalent

Discussion of Differences in Technological Characteristics

The VPAP Pediatric Face Mask shares fundamental technological characteristics with the predicate device (K101129), including similar indications for use, patient population (pediatric patients ≥7 years and >40 lbs/20 kg), use environment (hospital/institutional), and regulatory classification (Class II, Product Code CBK). Both devices are non-vented full face masks designed as patient interfaces for noninvasive ventilation, with similar mask and headgear materials (e.g., polycarbonate and silicone for the mask components), connector types (22 mm ISO 5356-1:2015), and single-patient use designation.

However, minor differences exist in certain technological characteristics, as detailed in the comparison table above. These include:

- **Operation Pressure Range**: The subject device supports 5-20 cmH_2O, while the predicate supports 4-20 cmH_2O. This slight difference in minimum pressure does not affect SE, as performance testing (including leakage and resistance to flow per internal standards) demonstrated comparable airflow delivery and seal integrity across the overlapping range.
- **Dead Space Volume**: The subject device has volumes of 103 mL (L size) and 138 mL (XL size), compared to the predicate's 245 mL (S size). The reduced dead space in the subject device does not raise new questions of substantial equivalence, as CO_2 rebreathing testing (per ISO 9360-1) confirmed equivalent gas exchange performance.
- **Resistance to Flow**: The subject device exhibits 0.7 cmH_2O at 50 L/min and 2.9 cmH_2O at 100 L/min, versus the predicate's 0.4 cmH_2O at 50 L/min and 1.2 cmH_2O at 100 L/min. This difference is attributable to design variations in mask geometry but does not impact SE, as flow resistance testing (per internal protocols) showed both devices maintain adequate ventilation without excessive pressure drop.
- **Size Configurations**: The subject device offers two pediatric sizes (L and XL), while the predicate offers S, M, and L sizes. The subject device's focused pediatric sizing does not affect SE, as dimensional verification and fit testing confirmed equivalent compatibility with patient interfaces and ventilators.
- **Materials (Headgear)**: The subject device's headgear includes SBR, nylon, thermoplastic polyurethane, and silicone corrugated tubing, compared to the predicate's nylon, Lycra polyester, polyurethane, and polyoxymethylene. These

variations are minor and do not affect substantial equivalence per biocompatibility testing (per ISO 10993-1, -5, -10, and -18) and chemical characterization.

These technological differences have been evaluated through comprehensive non-clinical performance testing, including leakage (per internal standards), resistance to flow (per internal standards), noise (per ISO 17510), dead space (per ISO 9360-1), biocompatibility (per ISO 10993 series), and volatile organic compounds/particulate matter emissions with toxicological risk assessment (per ISO 18562 series). The results confirm that the subject device performs comparably to the predicate device across all tested parameters, without raising different questions of substantial equivalence. The reference device (K102120) was specifically used to support the color additives in the headgear materials, further validating material compatibility.

Therefore, the VPAP Pediatric Face Mask is substantially equivalent to the predicate device.

7. Performance Data

Non-clinical testing was conducted to demonstrate substantial equivalence to the predicate device, including biocompatibility evaluations per ISO 10993 standards and emissions testing per ISO 18562 standards, along with general device performance assessments. The results from these tests confirm that the subject device performs comparably to the predicate device.

Biocompatibility testing included:

- Cytotoxicity testing (XTT assay) per ISO 10993-5, demonstrating acceptable cell viability.
- Sensitization testing (maximization test) per ISO 10993-10, showing no sensitization response.
- Irritation testing (intracutaneous reactivity) per ISO 10993-10, indicating no irritation.
- Chemical characterization per ISO 10993-18, confirming leachables and extractables within acceptable limits.

Emissions testing included:

- Particulate matter (PM) emissions per ISO 18562-2, with results below specified thresholds.
- Volatile organic compounds (VOC) emissions per ISO 18562-3, with results below specified thresholds.
- Toxicological risk assessment (TRA) based on the above emissions data per ISO 10993-17, yielding acceptable margins for potential exposure.

General performance testing included:

- Leakage testing per internal standards, which measures air leakage at specified pressures to verify seal integrity.
- Resistance to flow testing per internal standards, evaluating pressure drop across flow rates to ensure adequate airflow.
- Noise testing per internal standards, assessing sound levels during operation to confirm quiet performance.
- Dead space testing per ISO 9360-1, determining the volume of rebreathable gas to support ventilation efficiency, with results comparable to the predicate.

Transportation
The packaging ensures subject device integrity under ISTA 2A conditions, meeting FDA requirements for safe transportation. Minor carton deformations do not affect product safety or efficacy, supporting 510(k) compliance.

These non-clinical test results collectively support substantial equivalence to the predicate device.

8. Conclusion

The performance testing demonstrates that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.