April 23, 2025

Shenzhen Kingboom Technology Co., Ltd
℅ Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.
Room 1509, Jingting Building, Dongzhou Community
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K250697
Trade/Device Name: Electric Nasal Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: February 26, 2025
Received: March 7, 2025

Dear Reanny Wang:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*

K250697

Device Name

Electric nasal aspirator

Indications for Use *(Describe)*

The Electric Nasal Aspirator is intended for intermittent removal of nasal secretions and mucus from children (age 2-12 years old). This device is used in a home environment.

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.

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Traditional 510(k) Summary

510(k) number: K250697

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen Kingboom Technology Co., Ltd

Street Address: #201, 2nd fl, No.5, Tongxin Road, Pingdong Community, Pingdi Street, Longgang District

City: Shenzhen

State/ Province: Guangdong

Country: China

Telephone: +86-13590244726

Fax: /

Contact Person: Ma Qiang

Contact Title: General Manager

Contact Email: 156673750@qq.com

Date Prepared: Feb. 26, 2025

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name: Electric nasal aspirator

Model:	BC026, BC025, BC023
Common Name:	Powered suction pump
Classification Name:	Pump, portable, aspiration (powered)
Regulation:	21 CFR § 878.4780
Device Class:	Class 2
Product Code:	BTA

3. Identification of Predicate Device(s)

Manufacturer	Shenzhen XinLianFeng Technology Co., LTD
Legally Marketed Device	Electric nasal aspirator, model: BC026
510(K) Number	K222547

4. Description of Device

Electric nasal aspirator (model: BC026, BC025 and BC023) consists of main unit, and suction portion working together as one unit. The Electric nasal aspirator is a portable device which is intended for suction of nasal passages in children 2-12 years of age. The motor pump provides a negative pressure which removes nasal secretions. The motor pump operates on a rechargeable battery. The rechargeable battery can be charged from the external power adapter (not included in this device) through the provided charging line. The user interface consists of buttons and LED display, and the user can control the vacuum pressure through the button.

The differences between BC026, BC025, and BC023 are as follows:

1) BC026 has 5 suction levels, while BC023 and BC025 have 3 suction levels.
2) BC026 and BC023 have “Light” function for distracting and pacifying the child. BC025 does not have this function.
3) BC026 and BC023 can pause suction during the suction process. BC025 does not have this feature.
4) BC026 and BC023 have 4 buttons, BC025 has 2 buttons.
5) In addition, BC026, BC025, and BC023 have different Display, Size, Weight, and Appearance.

5. Indications for Use

The Electric nasal aspirator is intended for intermittent removal of nasal secretions and mucus from children (age 2-12 years old). This device is used in a home environment.

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

6.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Function test

All the test results demonstrate Electric nasal aspirator meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate devices.

6.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

7. Performance Summary

The devices conform to applicable standards as follow table:

Test Type	Standard Designation Number	FDA Recogniti on Status	Outcome for Device
Safety	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Yes	Conforms
EMC	IEC 60601-1-2:2020 IEC TR 60601-4-2: 2016	Yes	Conforms
Home healthcare environment	IEC 60601-1-11:2020	Yes	Conforms
Performance	Enterprise standard	Yes	Conforms
Biocompatibility	ISO 10993-1:2018	Yes	Conforms
Software	ANSI AAMI IEC 62304:2006/A1:2016	Yes	Conforms
Safety of Lithium battery	IEC 62133-2:2017	Yes	Conforms

Safety of lamps	IEC 62471: 2006	Yes	Conforms

Biocompatibility: The patient contact part (Funnel nozzle) utilized in the subject device is the same as the FDA cleared BC026 Electric nasal aspirator in K222547, their relationship to the patient for the subject device are identical in formation, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

8. Discussion of Comparison to Predicate Devices.

The Electric nasal aspirator submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics, materials, and performance to the cleared BC026 Electric nasal aspirator **K222547**. Differences between the subject and predicate device do not raise new questions of safety and effectiveness.

Device	**Subject device**	**Primary Predicate device**	**Comparison**
Manufacturer	Shenzhen Kingboom Technology Co., Ltd	Shenzhen XinLianFeng Technology Co., LTD	/
510(K) number	TBD	K222547	/
Product name	Electric nasal aspirator, model: BC026, BC025, BC023	Electric nasal aspirator, model: BC026	/
Classification	Class II Device, BTA (21 CFR § 878.4780)	Class II Device, BTA (21 CFR § 878.4780)	Identical
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	Identical
Indication for Use	The Electric nasal aspirator is intended for intermittent removal of nasal secretions and mucus from children (age 2-12 years old). This device is used in a home environment.	The Electric nasal aspirator is intended for intermittent removal of nasal secretions and mucus from children (age 2-12 years old). This device is used in a home environment.	Identical
Patient Population	Age 2-12 years old	Age 2-12 years old	Identical
Intended Environment	Home use	Home use	Identical
Device Description	The BC026, BC025, BC023 Electric nasal aspirator is a portable device which is intended for suction of nasal	The BC026 Electric nasal aspirator is a portable device which is intended for suction of nasal	Identical

Device	Subject device	Primary Predicate device	Comparison
	passages in children 2-12 years of age. The motor pump provides a negative pressure which removes nasal secretions.	passages in children 2-12 years of age. The motor pump provides a negative pressure which removes nasal secretions.	
Vacuum pressure	52-60Kpa	52-60Kpa	Identical
Music function	Yes	Yes	Identical
Light function	BC026 and BC023: yes BC025: No	Yes	Similar Note 1
Noise Level	＜80dBA	＜80dBA	Identical
Power consumption	2.2W	2.2W	Identical
Motor Type	3.7V DC	3.7V DC	Identical
Power Source	DC 3.7 V / 700mAh Rechargeable Li-ion battery	DC 3.7 V / 700mAh Rechargeable Li-ion battery	Identical
Device Dimension	BC026 and BC025: 160 (H) x 41 (L) x 41 (W)mm; BC023: 160 (H) x 41(L) x 39(W)mm	160 (H) x 41 (L) x 41 (W)mm	Similar Note 2
Weight	BC026: 320±5g BC025: 305±5g BC023: 317±5g	320±5g	
Tips Dimension (ψ)	OD4.3/ID2.4	OD4.3/ID2.4	Identical
Main Materials	ABS, PC, Silicone	ABS, PC, Silicone	Identical
Operating condition	5℃(41℉) to 40℃(104℉); 15% to 93% R.H.	5℃(41℉) to 40℃(104℉); 15% to 93% R.H.	Identical
Storage condition	-10°C(-23℉) to 70°C (158℉) ; 10% to 95% R.H.	-10°C(-23℉) to 70°C (158℉) ; 10% to 95% R.H.	Identical
Expected service life	2 years	2 years	Identical
Type BF	Type BF applied part	Type BF applied part	Identical

Device	Subject device	Primary Predicate device	Comparison
applied part			
Safety	IEC 60601-1 IEC 60601-1-11 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 62133-2 IEC 62471	Identical
EMC	IEC 60601-1-2	IEC 60601-1-2	Identical
Water-resistance	IP22	IP22	Identical
Biocompatibility	BC026, BC025, BC023 operate in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.	BC026 operates in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.	Identical
Contacted Parts	Silicone Tip (funnel nozzle)	Silicone Tip (funnel nozzle)	Identical
Material of contacted parts	Silicone	Silicone	Identical

The discussion of differences exist between the subject and predicate devices is listed as follows:

Note 1

Light function is used to distract and pacify the child. This function is optional and is not required for the device to achieve its intended use. Without the light function components, BC025 still complied with IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, which demonstrates substantial equivalence.

Note 2

Although there are some minor differences in the "Device Dimension" and "Weight" between the predicate device and BC025, BC023, the patient contact part (Funnel nozzle) is identical for all models. Therefore, differences in dimension and weight do not affect the substantial equivalence comparison.

9. Conclusions

Based on performance testing, comparison and analysis, the Electric nasal aspirator (model: BC026, BC025, BC023) subject device is substantially equivalent to the predicate device.