



March 13, 2026

Shenzhen Kingboom Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Rm. 1509, Jingting Bldg., Dongzhou Community
Guangming St., Guangming District
Shenzhen, Guangdong 518107
China

Re: K260147

Trade/Device Name: Electric nasal aspirator (BC026, BC025, BC023, BC028, BC029, BC036)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: January 20, 2026
Received: January 20, 2026

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 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260147

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Please provide the device trade name(s).

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Electric nasal aspirator (BC026, BC025, BC023, BC028, BC029, BC036)

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
☒ Over-The-Counter Use (21 CFR 801 Subpart C)

?

Traditional 510(k) Summary

510(k) number: K260147

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen Kingboom Technology Co., Ltd
Street Address: #201, 2nd floor, No.5, Tongxin Road, Pingdong Community, Pingdi Street, Longgang District
City: Shenzhen
State/ Province: Guangdong
Country: China
Telephone: +86-13590244726
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Contact Person: Ma Qiang
Contact Title: General Manager
Contact Email: 156673750@qq.com

Date Prepared: Jan. 15, 2026

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, BC028, BC029, BC036
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 Kingboom Technology Co., Ltd
Legally Marketed Device	Electric nasal aspirator, model: BC026, BC023, BC025
510(K) Number	K250697

4. **Description of Device**

Electric nasal aspirator (model: BC026, BC025, BC023, BC028, BC029, BC036) 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 is powered by a rechargeable battery. The rechargeable battery can be charged via an external power adapter(not included in this device) using the provided charging line. The user interface consists of buttons and LED display, and the user can control the air flow level through the button.

The differences between BC026, BC025, BC023, BC028, BC029 and BC036 are as follows:

- 1) The flow rate range of BC036 at different flow levels is different from other models.
- 2) BC025 and BC036 do not have "Light" function(used to distract and pacify the child), while other models do.
- 3) BC026, BC028, BC029 can pause suction during the suction process, while other models do not.
- 4) BC026, BC028, BC029 and BC023 have 4 buttons, BC025 and BC036 have 2 buttons.
- 5) In addition, BC026, BC028, BC029, BC025, BC036 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 TS 60601-4-2: 2024	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
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Biocompatibility: The patient contact part (suction nozzles) of subject device uses the same materials, material suppliers, and production processes as the FDA-cleared Electric nasal aspirator (K250697). The subject device's patient contact part is identical to that of the predicate device in terms of formation, processing, and surface characteristics, and no additional chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.) have been added.

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 Electric nasal aspirator **K250697**. Differences between the subject and predicate device do not affect the substantial equivalence comparison.

Device	Subject device	Primary Predicate device	Comparison
Manufacturer	Shenzhen Kingboom Technology Co., Ltd	Shenzhen Kingboom Technology Co., Ltd	/
510(K) number	TBD	K250697	/
Product name	Electric nasal aspirator, model: BC026, BC025, BC023, BC028, BC029, BC036	Electric nasal aspirator, model: BC026, BC025, BC023	/
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	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	The BC026, BC025 and BC023 Electric nasal aspirators are portable device which are intended for suction of nasal passages in children 2-12 years	Identical

Device	Subject device	Primary Predicate device	Comparison
	pressure which removes nasal secretions.	of age. The motor pump provides a negative pressure which removes nasal secretions.	
Vacuum pressure	50 to 62kPa	52-60kPa	Similar Note 1
Air Flow rate	BC026, BC029, BC028, BC023: ● Level1: 1.5-2.7L/min; ● Level 2: 2.8-3.7L/min; ● Level 3: 3.8~5L/min. BC025: ● Gentle flow level: 1.5-2.7L/min; ● Normal flow level: 2.8-3.7L/min; ● Strong flow level: 3.8~5L/min. BC036: ● Gentle flow level: 1.5-2.5L/min; ● Normal flow level: 2.6-3.5L/min; ● Strong flow level: 3.6~5L/min	No	
Music function	Yes	Yes	Identical
Light function	BC026 and BC023, BC028, BC029: yes BC025 and BC036: No	BC026 and BC023: yes BC025: No	Identical
Noise Level	<80dBA	<80dBA	Identical
Power consumption	2.55W	2.2W	Similar note 2
Motor Type	DC 3.0V	3.7V DC	Similar note 2
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 BC028: 156 (H) x41.5(L) x 38.5(W) mm BC029: 158 (H) x40.5(L) x 39.5(W) mm BC036: 156 (H) x41.5(L) x 40.5(W) mm	BC026 and BC025: 160 (H) x 41 (L) x 41 (W) mm; BC023: 160 (H) x 41(L) x 39(W) mm	Similar Note 3
Weight	BC026: 320±5g BC025, BC036: 305±5g BC023: 317±5g BC028, BC029: 300±5g	BC026: 320±5g BC025: 305±5g BC023: 317±5g	
Tips Dimension	Gourd Nozzle: OD5/ID3 Flat nozzle: OD3.8/ID2	OD4.3/ID2.4	Similar Note 4

Device	Subject device	Primary Predicate device	Comparison
(ψ)	Angle nozzle: OD4/ID2.3		
Main Materials	ABS, PC, Silicone	ABS, PC, Silicone	Identical
Operating condition	5°C(41°F) to 40°C(104°F); 15% to 93% R.H	5°C(41°F) to 40°C(104°F); 15% to 93% R.H.	Identical
Storage condition	-10°C(-23°F) to 70°C (158°F) ; 10% to 95% R.H.	-10°C(-23°F) to 70°C (158°F) ; 10% to 95% R.H.	Identical
Expected service life	2 years	2 years	Identical
Type BF applied part	Type BF applied part	Type BF applied part	Identical
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, BC028, BC029 and BC036 operate in conjunction with silicone nasal aspiration tips, which come into contact with nasal skin and mucosa for less than 24 hours.	BC026, BC025 and BC023 operates in conjunction with silicone nasal aspiration tips, which come into contact with nasal skin and mucosa for less than 24 hours.	Identical
Contacted Parts	Silicone nozzle	Silicone Tip (funnel nozzle)	Identical Only the name is different
Material of contacted parts	Silicone	Silicone	Identical

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

Note 1

Although the pressures of the subject device and the predicate device are slightly different, and the subject device adds the air flow rate to its performance, it can be evaluated that both electrical nasal aspirator provide sufficient suction to clean the nasal cavity. Moreover, the performance test results have shown that the subject device meets the necessary requirements in terms of suction properties. Therefore, the differences do not affect the substantial equivalence comparison.

Note 2:

Although the "Motor Type" and "Power consumption" between the predicate device and subject device are different, both the subject device and the predicate device comply with ANSI AAMI ES60601-1. So the differences do not affect the substantial equivalence comparison.

Note 3

Although there are some differences in the "Device Dimension" and "Weight" between the predicate device and BC028, BC029, and BC036, they all comply with ANSI AAMI ES60601-1 and IEC 60601-1-2, so the differences do not affect the substantial equivalence comparison.

Note 4:

Although the Tips Dimension of the subject device is different from that of the predicate device, the Tip's OD Dimension (Gourd Nozzle) of the subject device is slightly larger than that of the predicate device, while the Tip's OD Dimension (Flat nozzle and Angle nozzle) of the subject device is slightly smaller than that of the predicate device, in general, the OD size is with the similar range of the predicate device; The Tip's ID Dimension (Gourd Nozzle) of the subject device is slightly larger than that of the predicate device, while the Tip's ID Dimension (Flat nozzle and Angle nozzle) of the subject device is slightly smaller than that of the predicate device, in general, the ID size is with the similar range of predicate device. Besides, both the predicate device and the subject device are comply with the ANSI AAMI ES60601-1 and IEC 60601-1-11, so the differences do not affect the substantial equivalence comparison.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Electric nasal aspirator (model: BC026, BC025, BC023, BC028, BC029, BC036) is substantially equivalent to the predicate device.