May 12, 2026

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

Re: K260473
Trade/Device Name: Electrical Nasal Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: February 10, 2026
Received: February 12, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JOYCE C. LIN -S

for 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.	K260473

Please provide the device trade name(s).

Electric nasal aspirator (BC027, BC030, BC033, BC035, BC035B)

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

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☒ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☐ Adults (22 years old and greater)

510(k) Summary – K260473

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen Kingboom Technology Co., Ltd

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Telephone: +86-13590244726

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Contact Person: Ma Qiang

Contact Title: General Manager

Contact Email: 156673750@qq.com

Date Prepared: May 8, 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: BC027, BC30, BC033, BC035 and BC035B

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)

Predicate	Predicate Device	Reference Device
Manufacturer	Hetaida Technology Co., Ltd.	Shenzhen XinLianFeng Technology CO.,LTD
Legally Marketed Device	Electric nasal aspirator, model: HTD2601US, H2609AU	Electric nasal aspirator, model: BC026
510(K) Number	K241202	K222547
Product code	BTA	BTA
Device class	Class II	Class II

4. Description of Device

Electric nasal aspirator is consist of a separate main unit, suction chamber. 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 microprocessor provides control over vacuum pressure. The motor unit operates on a rechargeable battery (BC027, BC030, BC033), dry alkaline batteries and mains powered (BC035, BC035B). The rechargeable battery (BC027, BC030, BC033) can be charged from the external power adapter (not included in this device) through the provided charging line. The user interface consists of a panel keypad and LED display (BC027, BC030, BC033), and the user can control the vacuum pressure through the button.

The differences between BC027, BC030, BC033, BC035, BC035B are as follows:

Different items	**BC027**	**BC030**	**BC033**	**BC035**	**BC035B**
Vacuum range	≤68kPa	≤68kPa	≤68kPa	60 to 75 kPa	60 to 75 kPa
Flow level	5 levels; Level1: 2.8-3.7L/min; level 2: 3.8-4.7L/min; level 3: 4.8-5.7L/min level 4: 5.8-6.7L/min level 5: 6.8-9.0L/min	5 levels; Level1: 2.8-3.7L/min; level 2: 3.8-4.7L/min; level 3: 4.8-5.7L/min level 4: 5.8-6.7L/min level 5: 6.8-9.0L/min	5 levels; Level1: 2.8-3.7L/min; level 2: 3.8-4.7L/min; level 3: 4.8-5.7L/min level 4: 5.8-6.7L/min level 5: 6.8-9.0L/min	3 levels; Level1: 2.8-4.3L/min; level 2: 4.4-6.4L/min; level 3: 6.5-9.0L/min	3 levels; Level1: 2.8-4.3L/min; level 2: 4.4-6.4L/min; level 3: 6.5-9.0L/min
Charging Input	DC 5V 2.0A(Charge through provided USB 2.0/Type-C charging line and self purchased power adapter)	DC 5V 2.0A(Charge through provided USB 2.0/Type-C charging line and self purchased power adapter)	DC 5V 2.0A(Charge through provided USB 2.0/Type-C charging line and self purchased power adapter)	N/A	N/A
Power supply	DC 3.7 V / 2500mAh Rechargeable Li-ion battery	DC 3.7 V / 2500mAh Rechargeable Li-ion battery	DC 3.7 V / 2500mAh Rechargeable Li-ion battery	DC 5V 2.0A (Optional Power Supply Methods: Charge through provided USB 2.0/Type-C USB line and power adapter) or self purchased 4AA dry	DC 5V 2.0A (Charge through provided USB 2.0/Type-C USB line and power adapter) or self purchased 4AA dry alkaline batteries (LR6 1.5V)

				alkaline batteries (LR6 1.5V)	
Tips Dimension (ψ)	Gourd Nozzle：OD6/ID4.8 Pointed-nosed nozzle：OD4/ID2.3	Gourd Nozzle：OD6/ID4.8 Pointed-nosed nozzle：OD4/ID2.3	Gourd Nozzle：OD6/ID4.8 Pointed-nosed nozzle：OD4/ID2.3	Big funnel suction nozzle：OD5/ID3.2 Small funnel suction nozzle：OD4/ID2.3	suction nozzle：OD6.2/ID3
Light (used for distract and pacify the child)	yes	yes	yes	no	no
Pause suction function	yes	yes	yes	no	no
Button	Power button Flow level button Music button Light button	Power button Music button Flow level button Light button	Power button Flow rate & Volume Button Music button Light button	Power button	Power button
Display	LED digital display	LED digital display	LED digital display	LED beads display	LED beads display
Size:	130MM*90MM*50MM	116MM*96MM*50MM	102MM*94MM*51MM	114MM*95MM*52MM	114MM*95MM*52MM
weight	440±10g	463±10g	455±10g	283±5g	283±5g

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	Outcome for Device
Safety	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Conforms
EMC	IEC 60601-1-2:2020 IEC TR 60601-4-2: 2016	Conforms
Home healthcare environment	IEC 60601-1-11:2020	Conforms
Biocompatibility	ISO 10993-1:2018	Conforms
Software	ANSI AAMI IEC 62304:2006/A1:2016	Conforms
Safety of Lithium battery	IEC 62133-2:2017/A1:2021	Conforms
Safety of lamps	IEC 62471: 2006	Conforms

Biocompatibility: The patient contact part (Suction 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 Electric nasal aspirator **K241202** and **K222547**. Differences between the subject and predicate device and reference device do not raise new questions of safety and effectiveness.

Device	**Subject device**	**Predicate device**	**Reference Device**
Manufacturer	Shenzhen Kingboom Technology Co., Ltd	Hetaida Technology Co., Ltd.	Shenzhen XinLianFeng Technology Co., LTD
510(K) number	K260473	K241202	K222547
Product name	Electric nasal aspirator	Electric nasal aspirator	Electric nasal aspirator
Model	BC027, BC030, BC033, BC035, BC035B	HTD2601US, H2609AU	BC026
Classification	Class II Device, BTA (21 CFR § 878.4780)	Class II Device, BTA (21 CFR § 878.4780)	Class II Device, BTA (21 CFR § 878.4780)
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Type of use	Over-The-Counter Use	Over-The-Counter Use	Over-The-Counter Use
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.	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.
Patient Population	Age 2-12 years old	Age 2-12 years old	Age 2-12 years old
Intended Environment	Home use	Home use	Home use
Device Description	The BC027, BC030, BC033, BC035, BC035B Electric nasal aspirator is a device which is intended for suction of nasal passages in children 2-12 years of age. The device is designed with a separate main unit and suction chamber. The motor pump provides a negative pressure which removes nasal secretions.	The HTD2601US and H2609AU Electronic 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 BC026 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.
Vacuum pressure	BC027, BC030, BC033：≤ 68kPa BC035, BC035B：60 to 75 kPa	≤68kPa	52-60Kpa
Maximum flow value	BC027, BC030, BC033： Level1: 2.8-3.7L/min; level 2: 3.8-4.7L/min; level 3: 4.8-5.7L/min level 4: 5.8-6.7L/min level 5: 6.8-9.0L/min	≥1.6L/min	Not disclosed

Device	Subject device	Predicate device	Reference Device
	BC035, BC035B： Level1: 2.8-4.3L/min; level 2: 4.4-6.4L/min; level 3: 6.5-9.0L/min		
Music and Light function	BC027, BC030, BC033：Yes BC035, BC035B：No	No	Yes
Noise Level	＜80dBA	≤60dB	＜80dBA
Power consumption	3.75W	1.5W	2.2W
Motor Type	5.0V DC	3.7V DC	3.7V DC
Power Source	BC027, BC030, BC033： DC 3.7 V / 2500mAh Rechargeable Li-ion battery BC035, BC035B： self purchased 4AA dry alkaline batteries (LR6 1.5V) or DC 5V 2.0A (Charge through provided USB 2.0/Type-C USB line and power adapter)	DC 3.7 V / 500mAh Rechargeable Li-ion battery	DC 3.7 V / 700mAh Rechargeable Li-ion battery
Device Dimension	BC027： 130MM*90MM*50MM BC030： 116MM*96MM*50MM BC033； 102MM*94MM*51MM BC035, BC035B： 114MM*95MM*52MM	HTD2601US: 185 mm x 42 mm x 42 mm (Lx WxH) H2609AU: 191 mm x 42 mm x 42 mm (Lx WxH)	160 (H) x 41 (L) x 41 (W)mm
Weight	BC027： 440±10g BC030： 463±10g BC033； 455±10g BC035, BC035B： 283±5g	Approx.167g	320±5g
Tips Dimension (ψ)	BC027, BC030, BC033： Gourd Nozzle：OD6/ID4.8 Pointed-nosed nozzle：OD4/ID2.3 BC035： Big funnel suction nozzle：OD5/ID3.2 Small funnel suction nozzle：OD4/ID2.3 BC035B： suction nozzle：OD6.2/ID3	Type1: OD4.1mm/ID2.3mm Type2: OD7.9mm/ID3.0mm	OD4.3/ID2.4
Main Materials	ABS, PC, Silicone	ABS, PCTG, Silicone	ABS, PC, Silicone
Operating condition	5℃(41℉) to 40℃(104℉); 15% to 93% R.H.	5℃(41℉) to 40℃(104℉); ≤85% R.H.	5℃(41℉) to 40℃(104℉); 15% to 93% R.H.
Storage condition	-10°C(-23℉) to 70°C (158℉); 10% to 95% R.H.	-20°C(-4℉) to 55°C (131℉); ≤93% R.H.	-10°C(-23℉) to 70°C (158℉); 10% to 95% R.H.
Expected service life	2 years	5 years	2 years
Type BF applied part	Type BF applied part	Type BF applied part	Type BF applied part
Safety	IEC 60601-1 IEC 60601-1-11	ANSI AAMI ES60601-1 ANSI AAMI HA60601-1-	IEC 60601-1 IEC 60601-1-11

Device	Subject device	Predicate device	Reference Device
	IEC 62133-2 IEC 62471	11 IEC 62133-2	IEC 62133-2 IEC 62471
EMC	IEC 60601-1-2	ANSI AAMI IEC 60601-1-2	IEC 60601-1-2
Water-resistance	IP22	IP22	IP22
Biocompatibility	BC027, BC030, BC033, BC035, BC035B operates in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.	HTD2601US and H2609AU operates 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.
Standard of Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12
Contacted Parts	Silicone Tip (funnel nozzle)	Silicone Tip (funnel nozzle)	Silicone Tip (funnel nozzle)
Material of contacted parts	Silicone	Silicone	Silicone

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Electric nasal aspirator (model: BC027, BC030, BC033, BC035, BC035B) is substantially equivalent to the predicate device and reference device.