May 15, 2026

Shenzhen Root Innovation Technology Co., Ltd.
Haiyan Wen
Compliance Engineer
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Shenzhen, Guangdong 518219
China

Re: K260134
Trade/Device Name: Baby Nasal Aspirator (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02; BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA, KMA
Dated: January 16, 2026
Received: January 16, 2026

Dear Haiyan Wen:

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.	K260134

Please provide the device trade name(s).

Baby Nasal Aspirator (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02;
BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021)

Please provide your Indications for Use below.

The BN006 series (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02) 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 BN008 series (BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021) 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 additional spray function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.

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)

510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date Prepared: 2026-5-12

I. Submitter

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Ⅱ. Device

Device Trade Name: Baby Nasal Aspirator
Model(s): BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02; BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021
Regulation Name: Powered Suction Pump
Regulatory Class: II
Regulation Number: 878.4780
Product Code(s): BTA, KMA

Ⅲ. Predicate Device and Reference Device

Predicate #	Predicate Trade Name (Primary Predicate is listed first) Product	Product Code
K244033	Electric Nasal Aspirator	BTA
K241852	Nasal Aspirator（NS13）	BTA, KMA
K981602	DeVilbiss Model 6305D Heavy Duty AC Aspirator	BTA

Ⅳ. Device Description

The Baby Nasal Aspirator is an electrically powered nasal aspirator. There are two product series: the Baby Nasal Aspirator BN006 series (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02) and the Baby Nasal Aspirator BN008 series (BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021).The main differences between the BN006 series and the BN008 series are as follows:

1)The BN006 series does not include the spray function.

2)The BN008 series is equipped with a spray function.

The BN006 series (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02) consists of silicone nozzle which has three models (conical nozzle, flat nozzle, angled nozzle), collection cup, air tube, tweezers, charging cable-USB and aspirator body.

The BN008 series (BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021) consists of silicone nozzle which has two models (conical nozzle, flat nozzle) host, air tube and mucus collector. The Atomizer Module is used for moistening the nasal cavity.

The Baby 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. Different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.

Ⅴ. Indication for Use

The BN006 series (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02) 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 BN008 series (BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021) 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 additional spray function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.

Ⅵ. Comparison of Technological Characteristics with the Predicate Device

The subject devices have the same intended use as the Primary predicate device and Reference Device 1. The technological characteristics such as vacuum pressure is similar as the Reference Device 2 device. The technological characteristics such as music function and light function are similar as the Primary predicate device. Any minor differences between the subject device and the listed predicate device do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Comparison Element	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
510(k) Number	Pending	K244033	K241852	K981602	\
Trade name	Baby Nasal Aspirator	Electric Nasal Aspirator	Nasal Aspirator (NS13)	DeVilbiss Model 6305D Heavy Duty AC Aspirator	\
Regulation number	21 CFR § 878.4780	21 CFR § 878.4780	21 CFR § 878.4780	21 CFR § 878.4780	Same
Product code	BTA KMA	BTA	BTA KMA	BTA	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02：The Baby 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. BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021：The Baby 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 additional spray function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.	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 device is designed for using suction to remove nasal secretion and mucus in Children (age 2~12 years old) at home environment. The additional spray/irrigation function helps moisten and loosen/soften nasal secretions in Children (over 3 years old), making them easier to aspirate.	The DeVilbiss Model 630SD Heavy Duty AC Aspirator provides a vacuum source for home health care or institutional use. The product is used with a suction catheter or handle to clear secretions from the oral, nasal and pulmonary area. The intended target population for this device consists of both adult and pediatric patients. The intended environment for use of the product is in the patient's home or within an institutional setting on the order of a physician.	Same as the Primary Predicate Device and Reference Device 1
Model	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02; BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021	NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610	NS13	6305D	\
Patient Population	Age 2-12 years old；spray function is intended for children over 3 years old	Age 2-12 years old	Age 2-12 years old；spray function is intended for children over 3 years old	Adult and pediatric patients	Same
Vacuum pressure	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02：66 Kpa (±4 Kpa) BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021：72 Kpa (±3 Kpa)	52-60Kpa	100-120 mmHg	22.0 in. Hg（equal to 75 kPa）	Similar to the Reference Device 2
Spray Capacity	0.2~0.3 ml/6sec	\	0.4~0.5 ml/10sec	\	Similar to the Reference Device 1

Music function	Yes	Yes	\	\	Same as the Primary Predicate Device
Light function	Yes	Yes	\	\	Same as the Primary Predicate Device
Power consumption	5W	5W	\	\	Same as the Primary Predicate Device
Motor Type	3.7V DC	3.7V DC	\	\	Same as the Primary Predicate Device
Power Source	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02：DC 3.7 V / 2600mAh Rechargeable Li-ion battery BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021：DC 3.7 V / 2500mAh Rechargeable Li-ion battery	DC 3.7 V / 2500mAh Rechargeable Li-ion battery	\	\	Similar to the Primary Predicate Device
Device Dimension	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02：105mm *75mm*51mm BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021：126mm*70mm*127 mm	W95 x H45mm	\	\	Different Note 1
Weight	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02：276g BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021：480±5g	235g	Approx.158g (Exclude batteries)	\	

Tips Dimension (ψ)	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02： Conical nozzle: OD 4.0 / ID 2.0 mm Flat nozzle/Angled nozzle OD 4.0 / ID 2.0 mm BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021： Conical nozzle: OD 3.5 / ID 3.0 mm Flat nozzle: OD 3.0 / ID 2.0 mm	Flat nozzle/Angled nozzle: OD 4.0 / ID 2.0 mm Conical nozzle: OD 4.0 / ID 2.0 mm	Gourd shape tip: Φ5xΦ2.6x35.68 Long tip: Φ5xΦ3x35.68 Short tip: Φ5.68xΦ3x27.68	\	Similar to the Primary Predicate Device
Main Materials	ABS, PS, Silicone	ABS, PS, Silicone	\	\	Same as the Primary Predicate Device
Operating condition	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02： Temperature: 5°C(41°F) to 40°C(104°F) Humidity: 15% to 93% R.H. Atmospheric pressure: 700-1060hPa BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021： Temperature: 5°C(41°F) to 40°C(104°F) Humidity: 15% to 85% R.H. Atmospheric pressure: 700-1060hPa	Temperature: 5°C(41°F) to 40°C(104°F) Humidity: 15% to 93% R.H. Atmospheric pressure: 700-1060hPa	Temperature: 16°C ~ 35°C (60.8°F ~ 95°F) Humidity: 15%~85% RH	\	Similar to the Primary Predicate Device
Storage condition	BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02： Temperature：-10°C(-23°F) to 70°C (158°F) Humidity： 10% to 95% R.H. Atmospheric pressure: 700-1060hPa BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021： Temperature: 5°C(41°F) to 40°C(104°F) Humidity: 15% to 85% R.H. Atmospheric pressure: 700-1060hPa	Temperature：-10°C(-23°F) to 70°C (158°F) Humidity： 10% to 95% R.H. Atmospheric pressure: 700-1060hPa	Temperature: - 25°C ~ 55°C (-13°F ~ 131°F) Humidity: 15% to 85% R.H.	\	Similar to the Primary Predicate Device
Expected service life	2 years	2 years	\	\	Same as the Primary Predicate Device

Standard of Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	\	Same as Primary Predicate Device
Safety	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	\	Same as Primary Predicate Device
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	\	Same as Primary Predicate Device

Ⅶ. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing Within a Risk Management Process", as follows:

- ISO 10993-5:2009, Biological evaluation of medical devices–Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices–Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

3) Battery Safety

- IEC 62133-2 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

4) Software Verification and Validation

Software documentation consistent with ***basic documentation level*** was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels

5) Bench testing

Appearance Test: In order assure the physical/visual verification of Electric Nasal Aspirator, we have conducted the product appearance test (color, dimension etc.).

Performance Test: In order to verify and assure the performance of Electric Nasal Aspirator, we have conducted the product performance test (vacuum pressure, noise level, flow rate, tubing bending resistance, Spray Capacity, Tips Dimension etc.).

Ⅷ. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Electric Nasal Aspirator is as safe, as effective, and performs as well as the legally marketed predicate device.