May 16, 2025

Shenzhen Desida Technology Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K244033
Trade/Device Name: Electric Nasal Aspirator
(NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 18, 2025
Received: April 18, 2025

Dear Youshan Gong:

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,

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

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)*

K244033

Device Name

Electric Nasal Aspirator (NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610)

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary of K244033

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

**Date Prepared: 2025-5-15**

## I. Submitter

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## II. Device

**Name of Device:** Electric Nasal Aspirator
**Model(s):** NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610
**Regulation Name:** Powered Suction Pump
**Regulatory Class:** II
**Product Code:** BTA
**Regulation Number:** 21 CRF 878.4780

## III. Predicate Device and Reference Device

### ➢ Predicate Device

| Manufacturer | Predicate Device | 510(k) Number |
|---|---|---|
| Shenzhen Desida Technology Co., Ltd. | Baby Nasal Aspirator (model: KA1006,KA1001,KA1005,NASA005,NASA006,NASA008,NASA009) | K233901 |

## IV. Device Description

Electric Nasal Aspirator 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 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. Three different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.

## V. 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.

## VI. Materials

| Model | Contacted Component Name | Materials |
|---|---|---|
| NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610 | Enclosure | PC, ABS, with seven colour toners |
| | Tips (Conical nozzle, Flat nozzle, Angled nozzle) | Silicone |

## VII.Comparison of Technological Characteristics With the Predicate Device

The Electric Nasal Aspirator has the same intended use as the predicate device. The technological characteristics such as vacuum pressure, music function, light function and noise level are same as the predicate device. Any minor differences between the subject device and the listed predicate device do no 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.
Therefore, the Electric Nasal Aspirator may be found substantially equivalent to its predicate device.

| Comparison Elements | Subject Device | Predicate Device | Remark |
|---|---|---|---|
| 510(k) Number | K244033 | K233901 | / |
| Trade name | Electric Nasal Aspirator | Baby Nasal Aspirator | / |
| Manufacturer | Shenzhen Desida Technology Co., Ltd. | Shenzhen Desida Technology Co., Ltd. | / |
| Regulation number | 21 CFR § 878.4780 | 21 CFR § 878.4780 | Same |
| Product code | BTA | BTA | Same |
| Device classification | Class II | Class II | Same |

| **Comparison Elements** | **Subject Device** | **Predicate Device** | **Remark** |
|---|---|---|---|
| Indication for use/ Intended 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. | Baby Nasal Aspirator is intended for intermittent removal of nasal secretions and mucus from children (age 2~12 years old). This device is ued in a home environment. | Same |
| Prescription or OTC | OTC | OTC | Same |
| Model | NASA601,NASA602,NASA603,NASA605,NASA606,NASA608,NASA610 | KA1006,KA1001,KA1005,NASA005,NASA006,NASA008,NASA009 | Different **Note 1** |
| Patient Population | Age 2-12 years old | Age 2-12 years old | Same |
| Vacuum pressure | 52-60Kpa | 52-60Kpa | Same |
| Music function | Yes | Yes | Same |
| Light function | Yes | Yes | Same |
| Power consumption | 5W | 2W_max | Different **Note 2** |
| Motor Type | 3.7V DC | 3.7V DC | Same |
| Power Source | DC 3.7 V / 2500mAh Rechargeable Li-ion battery | DC 3.7 V / 700mAh Rechargeable Li-ion battery | Different **Note 2** |
| Device Dimension | W95 x H45mm | L 188×W 40×H 75mm | Different **Note 3** |
| Weight | 235g | 155±5g | |
| Flow rate | 3.3 - 6.0 L/min | 2.5-2.7 L/min | Different **Note 4** |
| Structural composition | It is component of silicone nozzle, collection cup, air tube, tweezers, charging cable-USB and aspirator main body. | It is component of silicone nozzle, collection cup, charging cable-USB | Different **Note 5** |

| Comparison Elements | Subject Device | Predicate Device | Remark |
|---|---|---|---|
| | | and aspirator body. | |
| Tips Dimension (ψ) | Flat nozzle/Angled nozzle OD 4.0 / ID 2.0 mm<br>Conical nozzle: OD 4.0 / ID 2.0 mm | Flating tip, Bevel tip: OD 4.0 / ID 2.0 mm<br>Calabash tip: OD 5.0 / ID 2.6 mm | Same |
| Main Materials | ABS, PC, Silicone | ABS, PC, Silicone | Same |
| Operating condition | 5℃(41℉) to 40℃(104℉); 15% to 93% R.H. | 5℃(41℉) to 40℃(104℉); 15% to 93% R.H. | Same |
| 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. | Same |
| Expected service life | 2 years | 2 years | Same |
| Type BF applied part | Type BF applied part | Type BF applied part | Same |
| Water-resist | IP22 | IP22 | Same |
| Contacted Parts | Silicone Tip | Silicone Tip | Same |
| Material of contacted parts | Silicone | Silicone | Same |
| Biocompatibility | Electric Nasal Aspirator operates in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.<br>● In Vitro Cytotoxicity Test Report<br>● Skin Sensitization Test Report<br>● Skin Irritation Test Report | Baby Nasal Aspirator operates in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.<br>● In Vitro Cytotoxicity Test Report<br>● Skin Sensitization Test Report<br>● Skin Irritation | Same |

| Comparison Elements | Subject Device | Predicate Device | Remark |
|---|---|---|---|
| | | Test Report | |
| Safety | IEC 60601-1<br>IEC 60601-1-11<br>IEC 62133-2<br>IEC 62471 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 62133-2<br>IEC 62471 | Same |
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | Same |

Note 1:
Though the model is different from the predicate device, this difference is insignificant and does not raise any safety or effectiveness problems. NASA601, NASA603, NASA605, NASA606, NASA608, NASA610 are completely consistent with the main model NASA602 in terms of circuit design, PCB layout, key components, power supply method, and appearance, only the colors of enclosure are different.

Note 2:
Though the power consumption and power source of subject device is different from the predicate device, the subject device is comply with IEC 62133-2, IEC 60601-1 and IEC 60601-1-2 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:
Though the device dimension and weight are different from the predicate device, we conducted the Electric Nasal Aspirator Product Performance Test, the product performance can meet the requirement, this difference is insignificant and do not raise any safety or effectiveness problems.

Note 4:
The device flow rate is different from the predicate device, and the subject device is different from the predicate device in terms of product structure. The subject device has the structure of air tube, while the flow rate mainly refers to the volume of secretions inhaled per unit time. The higher the flow rate, the more nasal secretions can be removed per unit time, which can shorten the operation time and may improve cleaning efficiency. Since the subject device has more air tube structure than the predicate device, the performance of the subject device may be reduced at the same flow rate. Although the current flow rate of the subject devices is higher than predicate device, their vacuum pressure range is the same, both 52-60 kPa, which not only ensures effective flow rate but also reduces the risk of mucosal damage. Suction levels and vacuum pressure range have been designed to take into account the vulnerability of children's nasal mucosa to avoid damage due to excessive pressure. Performance testing was completed to verify the product requirements; the differences above do not raise different questions of safety or effectiveness.

Note 5:
The structural composition of subject device is different from the predicate device, the subject device has two more components than the predicate device (i.e., air tube and tweezer):

For air tube: The performance tests results support the safety and effectiveness of the device.

For tweezer: Tweezer is an accessory. If necessary, users can use tweezer to remove hard secretions from the nasal cavity. Tweezer is an additional auxiliary tool for users to choose to use. It does not raise any concerns of safety or effectiveness.

## VIII. Performance Data

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

**1) Biocompatibility Testing**

The biocompatibility evaluation for the body-contacting components of the subject device 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 recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices –Part 10: Tests for skin sensitization
- ISO 10993-23, 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 to verify and assure the performance of Electric Nasal Aspirator, we have conducted the product appearance test (color, dimension, weight, 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, etc.).

## IX. 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.