April 14, 2026

Shenzhen Dongjiang Technology Co., Ltd.
Jenny Wu
Primary Correspndent
Room 301, Building 9, No. 6 Hongji Road, Longxin Community
Baolong Street
Shenzhen, Guangdong 518000
China

Re: K253107
Trade/Device Name: Electric Nasal Aspirator (DT10, DT50, DX80, DX85, DX86 and DX90)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 10, 2025
Received: September 24, 2025

Dear Jenny Wu:

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

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.

510(k) Number *(if known)*
K253107

Device Name
Electric Nasal Aspirator (DT10, DT50, DX80, DX85, DX86, DX90)

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.

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510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	August. 15, 2025
Manufacturer information	Submitter's Name: Shenzhen Dongjiang Technology Co., Ltd. Address: Room 301, Building 9, No. 6 Hongji Road, Longxin Community, Baolong Street, Longgang District, Shenzhen, Guangdong Province, China Contact person: Wei Junjie TEL: +86 13316967567
Submission Correspondent	Contact person: Ms Jenny.Wu E-Mail: jenny.wu@aivikon.com Tel: +8613316972203
Establishment registration number	3021595514

2 Device Information

Type of 510(k)	Traditional
Common name of the device	Powered Suction Pump
Trade name of the device	Electric Nasal Aspirator
Type/Model of the device	DT10 and DT50, DX80, DX85, DX86 and DX90
Classification information	Classification panel: General & Plastic Surgery Classification name: pump, portable, aspiration (manual or powered) Regulation Number: 21 CFR § 878.4780 Device Class: II Product Code: BTA

3 Primary predicate Device Information and Reference predicate Device Information

Sponsor:	Shenzhen Desida Technology Co., Ltd.

Device:	Electric Nasal Aspirator
510(K) Number:	K244033
Product code:	BTA
Approval date:	05/16/2025

4 Device Descriptions

The Electric Nasal Aspirator (model: DT10 and DT50) consists of silicone tip, collection cup, air tube, main unit and charging cable-USB.

The Electric nasal aspirator (model: DX80, DX85, DX86 and DX90) consists of main unit, and suction portion (silicone tip and collection cup connecting main unit directly) working together as one unit. The 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 cable-USB.

The user interface consists of buttons and LED display, and the user can control the vacuum pressure through the button. The different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.

The device is a multi-use device for single user it is non-sterile.

The differences between DT10, DT50, DX80, DX85, DX86 and DX90 are as follows:

1) DT10, DT50 are hand-held device which has air tube to connect the suction portion and the main unit, while DX80, DX85, DX86 and DX90 are portable.

2) DT10, DT50 and DX90 use two type tips (Round tip, Straight tip) and DX80, DX85, DX86 use three type tips (gourd type tip, funnel type flat tip, funnel type bevel tip).

3) DT10, DT50 have 6 Suction Level, DX80, DX85, DX86 and DX90 have 5 Suction Level. DT10, DT50 have 3 Sound Level, DX80, DX85, DX86 and DX90 have 2 Sound Level.

4) DT10, DT50 use different battery models, DX80, DX85, DX86 and DX90 use the same battery model.

5) In addition, DT10, DT50, DX80, DX85, DX86 and DX90 have different Display, Size, Weight, and Appearance.

5 Intended Use/ 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 Intended user

children (age 2~12 years old)

7 Work principle

The device utilizes a motor pump to generate negative pressure in the suction system, which allows nasal secretions to flow into the device collection cup.

8 SE Comparisons

The subject device Electric Nasal Aspirator has the same intended use and indications for use as the predicate devices and uses equivalent overall design and operating principals as the predicate devices. 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 subject device may be found substantially equivalent to its predicate device.The subject device is compared

with the following Predicate Devices in terms of intended use, design, specifications, and performance :

Comparison Elements	**Subject Device**(K253107)	**Predicate Device**(K244033)	**Remark**
Trade name	Electric Nasal Aspirator	Electric Nasal Aspirator	/
Model	DT10, DT50; DX90, DX86, DX85, DX80	NASA601, NASA602, NASA603, NASA605, NASA606, NASA608, NASA610	N/A
Manufacturer	Shenzhen Dongjiang 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
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.	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.	Same
Prescription or OTC	OTC	OTC	Same
Patient Population	Age 2-12 years old	Age 2-12 years old	Same
Vacuum pressure	52 to 60Kpa	52-60Kpa	Same
Flow rate	DT10 and DT50: 3.0 to 5.8L/min (error: ±0.2L/min) DX80, DX85, DX86 and DX90: 2.0 to 2.8 L/min (error: ±0.2L/min)	3.3 - 6.0 L/min	Different **Note 1**
Music function	Yes	Yes	Same
Light function	Yes	Yes	Same
Power consumption	DT10 and DT50: 2.96W DX80, DX85, DX86 and DX90: 2.2W	5W	Different **Note 2**
Motor Type	3.7V DC	3.7V DC	Same
Power Source	DT10: DC 3.7V/ 2000mAh Rechargeable Li-ion battery DT50: DC 3.7V/ 3000mAh Rechargeable Li-ion battery DX80, DX85, DX86, and	DC 3.7 V / 2500mAh Rechargeable Li-ion battery	Different **Note 2**

	DX90: DC 3.7V/ 750mAh Rechargeable Li-ion battery		
Device Dimension	DT10: D135×H105mm DT50: L156×W117×H104mm DX80: L146*W55*H54mm DX85: L173×W40×H41mm DX86: L161×W40×H41mm DX90: L122*W61*H46mm	W95 x H45mm	Different **Note 3**
Weight	DT10: 425.8g DT50: 750g DX80: 185g DX86: 185g DX85: 162g DX90: 139g	235g	Different **Note 3**
Structural composition	It is component of silicone nozzle, collection cup, air tube (only for DT10, DT50, Not for DX80, DX85, DX86, and DX90), charging cable-USB and aspirator main body.	It is component of silicone nozzle, collection cup, air tube, tweezers, charging cable-USB and aspirator main body.	Different **Note 4**
Tips Dimension (ψ)	Round tip and Straight tip: OD 8.0/ID 3.0 mm Gourd tip: OD 4.8/ ID 2.8 mm Funnel tip: OD 4.0/ ID 2.6 mm	Flat nozzle/Angled nozzle OD 4.0 / ID 2.0 mm Conical nozzle: OD 4.0 / ID 2.0 mm	Different **Note 5**
Main Materials	ABS, Silicone, PC	ABS, PC, Silicone	Same
Operating condition	Ambient temperature: 0℃～35℃ Relative humidity (RH): 15%-85% Atmospheric pressure: 700 hPa-1060 hPa	5℃ (41℉) to 40℃ (104℉); 15% to 93% R.H.	Same
Storage condition	Ambient temperature: -20℃～55℃ Relative humidity (RH): 10%-95% Atmospheric pressure: 700 hPa-1060 hPa	-10°C (-23℉) to 70°C (158℉); 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. ● In Vitro Cytotoxicity Test Report ● Skin Sensitization Test Report ● Skin Irritation Test Report	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. ● In Vitro Cytotoxicity Test Report ● Skin Sensitization Test Report ● Skin Irritation Test Report	Same
Safety	DT10, DT50: IEC 60601-1 IEC 60601-1-11 IEC 62133-2 IEC 62471 DX80, DX85, DX86, DX90: IEC 60601-1 IEC 60601-1-11 IEC 62133-2	IEC 60601-1 IEC 60601-1-11 IEC 62133-2 IEC 62471	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same

Note 1:

The device flow rate is different from the predicate device since the subject device is different from the predicate device in terms of product structure. The subject device (DT10, DT50) 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.

Although the current flow rate of the subject devices (DX80, DX85, DX86, DX90) is different from the predicate device. The flow rate range is within the range of the predicate. Their vacuum pressure range is the same, all 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 2:

Though the power consumption and power source of subject device is different from the predicate device, the subject device complies 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 structural composition of subject device (DT10, DT50) is same as the predicate device. The structural composition of subject device (DX80, DX85, DX86, DX90) is different from the predicate device, which has no air tube component.

Note 5:

The Tips Dimensions are different from the predicate device.
These structure difference and the Tips Dimensions may affect the vacuum pressure and flow rate performance parameters. All the performance tests results support the safety and effectiveness of the device. It does not raise any concerns of safety or effectiveness.

These different technological characteristics of the subject devices do not raise different questions of safety and effectiveness. Thus, the subject device is Substantially Equivalent (SE) to the predicate devices which is legally marketed in US.

9 Non-Clinical Test Summary

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

1) Biocompatibility Testing

The patient contact part (Round Tips, Straight Tips, Gourd-Type Tips, Funnel-Type Flat Tips, Funnel-Type Bevel Tips) utilized in the subject device is not different from the models. All the components of the subject device are identical in processing and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). only the difference is appearance formation and geometry.

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 Electromagnetic Compatibility

Electrical safety and EMC testing was performed 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 1-11: 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
- ✧ IEC 62471 Photobiological safety of lamps and lamp systems

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) Performance-Bench

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

- Product life test
- Suction test
- Flow rate test
- Automatic power-off test
- Noise test

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

5) 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.

6) Animal Data

No animal studies were necessary for the subject device.

8 Clinical Data

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

10 Conclusions

The subject device:

Based on performance testing, comparison and analysis, Electric Nasal Aspirator (Model:

DT10, DT50, DX80, DX85, DX86, DX90) is respectively substantially equivalent to the predicate device (Electric Nasal Aspirator) manufactured by Shenzhen Desida Technology Co., Ltd. (K244033).