July 1, 2024

Hetaida Technology Co., Ltd.
Tom Chen
General Manager
Rm 801, 802, 803, 804, 901, 2# Bldg Scientific Research Ctr
Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town
Dongguan, Guangdong 523423
China

Re: K241202
Trade/Device Name: Electric nasal aspirator (HTD2601US, H2609AU)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 19, 2024
Received: April 30, 2024

Dear Tom Chen:

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.

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

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)*

K241202

Device Name

Electric nasal aspirator (HTD2601US, H2609AU)

Indications for Use *(Describe)*

The Electronic 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.

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# 510(k) Summary

[As required by 21 CFR 807.92]

## 1. Submission Information

| | |
|---|---|
| 510(k) Number: | K241202 |
| Date: | April 19th, 2024 |
| Type of 510(k) Submission: | Traditional 510(k) |
| Basis for 510(k) Submission: | New device |
| Submitter/Manufacturer: | Hetaida Technology Co., Ltd.<br>Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R.China<br>Tel: +86-0769-83326886<br>E-mail: tomchen@hetaida.com.cn |
| Contactor: | Tom Chen<br>Hetaida Technology Co., Ltd.<br>Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R.China<br>E-mail: tomchen@hetaida.com.cn<br>Tel: +86-0769-83326886 |

## 2. Device Description

| | |
|---|---|
| Proprietary Name: | Electric nasal aspirator |
| Model Name: | HTD2601US, H2609AU |
| Classification Name: | Pump, Portable, Aspiration (Manual Or Powered) |
| Product Code: | BTA |
| Device Class: | 2 |
| Regulation Number: | 21 CFR § 878.4780 |
| Review Panel: | General & Plastic Surgery |
| Indications for use: | The Electronic 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. |
| Device Description: | Electric nasal aspirator consists of main unit, and the suction portion working together as one unit. The 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 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. |

## 3. Predicate Device Identification

| | |
|---|---|
| 510(k) Number: | K222547 |
| Product Name: | Electric nasal aspirator |
| Submitter: | Shenzhen XinLianFeng Technology CO.,LTD |

**4. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

**4.1 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
- Usability
- Function test
- Biocompatibility 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.

**4.2 Clinical Testing**

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

**5. Substantially Equivalent Comparison**

| **Parameters** | | **New Device** | **Predicate Device** | **Remark** |
|---|---|---|---|---|
| 1. | 510(k) Number: | K241202 | K222547 | -- |
| 2. | Marketing clearance date: | No | October 20, 2022 | -- |
| 3. | Device Name | Electric nasal aspirator | Electric nasal aspirator | -- |
| 4. | Model | HTD2601US, H2609AU | BC026 (Predicate device Labeling is BC023) | -- |
| 5. | 510(k) Owner | Hetaida Technology Co., Ltd. | Shenzhen XinLianFeng Technology CO.,LTD | -- |
| 6. | Classification | Class II Device, BTA (21 CFR § 878.4780) | Class II Device, BTA (21 CFR § 878.4780) | Same |
| 7. | Classification Panel | General & Plastic Surgery | General & Plastic Surgery | Same |
| 8. | Type of use | Over-The-Counter Use | Over-The-Counter Use | Same |
| 9. | Indications for Use | The Electronic 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 Electronic 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 |
| 10. | Patient Population | Age 2-12 years old | Age 2-12 years old | Same |
| 11. | Intended Environment | Home use | Home use | Same |
| 12. | Device Description | 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 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. | Same |

| | | | | |
|---|---|---|---|---|
| 13. | Vacuum pressure | ≤68kPa | 52-60Kpa | Different Note 1 |
| 14. | Maximum flow value | ≥1.6L/min | No | |
| 15. | Noise Level | ≤60dB | ＜80dBA | Similar |
| 16. | Power consumption | 1.5W | 2.2W | Different Note 2 |
| 17. | Motor Type | 3.7V DC | 3.7V DC | |
| 18. | Power Source | DC 3.7 V / 500mAh<br>Rechargeable Li-ion battery | DC 3.7 V / 700mAh<br>Rechargeable Li-ion battery | |
| 19. | Device Dimension | HTD2601US: 185 mm x 42 mm x 42 mm (Lx WxH)<br>H2609AU: 191 mm x 42 mm x 42 mm (Lx WxH) | 160 (H) x 41 (L) x 41 (W)mm | Different Note 3 |
| 20. | Weight | Approx.167g | 320±5g | |
| 21. | Tips Dimension (ψ) | Type1: OD4.1mm/ID2.3mm<br>Type2: OD7.9mm/ID3.0mm | OD4.3/ID2.4 | Different Note 4 |
| 22. | Main Materials | ABS, PCTG, Silicone | ABS, PC, Silicone | Different Note 5 |
| 23. | Operating condition | 5°C～40°C(41°F～104°F);<br>≤85% R.H.; | 5°C(41°F) to 40°C(104°F);<br>15% to 93% R.H. | Similar |
| 24. | Storage condition | -20°C～55°C(-4°F～131°F);<br>≤93% R.H.; | -10°C(-23°F) to 70°C<br>(158°F) ; 10% to 95% R.H. | Different Note 6 |
| 25. | Expected service life | 5 years | 2 years | Different Note 7 |
| 26. | Type BF applied part | Type BF applied part | Type BF applied part | Same |
| 27. | Safety | ANSI AAMI ES60601-1<br>ANSI AAMI HA60601-1-11<br>IEC 60601-1-6<br>IEC 62133-2 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 62133-2<br>IEC 62471 | Note 8 |
| 28. | EMC | ANSI AAMI IEC 60601-1-2 | IEC 60601-1-2 | |
| 29. | Water-resistance | IP22 | IP22 | Same |
| 30. | Biocompatibility | 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. | Note 9 |
| 31. | Standard of Biocompatibility | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-12 | Note 9 |
| 32. | Contacted Parts | Silicone Tip (funnel nozzle) | Silicone Tip (funnel nozzle) | Same |
| 33. | Material of contacted parts | Silicone | Silicone | Same |

The discussion of differences exist between the proposed and predicate devices is listed as follows:

**Note 1**: Although the pressures of the proposed device and the predicate device are slightly different, and the proposed device adds the flow rate to performance, both can evaluate that the nasal aspirator provides sufficient suction to clean the nasal cavity. Moreover, the performance test results have shown that the

proposed device meets the necessary requirements in terms of suction level properties and daily application. Therefore, the differences do not affect the safety and effectiveness.

**Note 2**: Although the Power consumption and Power Source between the proposed device and the predicate device are different, the battery of the proposed device is widely available on the market and has been tested to the IEC 62133-2. In addition, the proposed device has been tested to AAMI/ANSI ES60601-1 and IEC 60601-1-2. Therefore, the difference does not raise any new safety and effectiveness issues.

**Note 3**: Although the Device Dimension and the Weight between the proposed device and the predicate device are different, they are all complied with IEC 60601-1 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness.

**Note 4**: Although the Tips Dimension of proposed device is different from that of predicate device, the Tip's OD Dimension (Type 2) of proposed device is larger than that of predicate device, but the Tip's OD Dimension (Type 1) of proposed device is slightly smaller than that of predicate device, in general, the OD size is with the similar range of the predicate device;

The Tip's ID Dimension (Type 2) of the proposed device is slightly larger than that of predicate device, but the Tip's ID Dimension (Type 1) of proposed device is slightly smaller than that of predicate device, in general, the ID size is with the similar range of predicate device. Besides, both the predicate device and proposed device are complied with the ANSI AAMI ES60601-1 and ANSI AAMI HA60601-1-11, so the differences do not affect the safety and effectiveness.

**Note 5**: Although the materials of the proposed device and the predicate device are slightly different, the PCTG is BPA-free and safer than PC. Moreover, the biocompatibility test results have shown that the proposed device and the predicate device meet the necessary requirements in terms of biocompatibility.

**Note 6**: The Storage environment of proposed device is different from that of predicate devices, but they all complied with the IEC 60601-1-11 and IEC 60601-1, so the difference will not raise any new safety and effectiveness issues.

**Note 7**: Although the Expected service life of the proposed device and the predicate device are slightly different, the service life of the proposed device is longer than that of predicate device. Moreover, the life test results have shown that the service life of proposed device meets the requirements in terms of 5 years. Therefore, the difference does not raise any new safety and effectiveness issues.

**Note 8**: Although the Safety and EMC standards of the proposed device and the predicate device are slightly different, the proposed device does not have the Music and Light function, so there is no need to meet the IEC 62471, and complied with the IEC 60601-1-6 for usability is also important. Therefore, the difference does not raise any new safety and effectiveness issues.

**Note 9**: Although the Biocompatibility standards of the proposed device and the predicate device are slightly different, the standard ISO 10993-10 has undergone a new revision that has resulted in the addition of standard ISO 10993-23, so should also comply with the new revision and the new standard for biocompatibility.

The proposed device has the same indication for use as the predicate device as well as comparable technical and biocompatibility properties and characteristics, and the minor differences don’t raise any additional questions for safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.

**6. Non-clinical Testing Summary**

Bench tests were conducted to verify that the proposed device met all requirements. The test results demonstrated that the proposed device complies with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012+A2:2021 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)];
- ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)];
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes;
- IEC 62133-2 Edition1.0 2017-02 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;
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization,
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation.
- Performance tests: Negative pressure measuring, Maximum flow rate, Automatic power-off, and Noise test.

**7. Conclusion**

The conclusion drawn from the non-clinical testing, comparison, and analysis demonstrates that the subject device in 510(k) submission, the subject device is substantially equivalent to the legally marketed predicate device K222547.