March 20, 2024

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: K233901
Trade/Device Name: Baby Nasal Aspirator (KA1006, KA1001, KA1005, NASA005, NASA006, NASA008, NASA009)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: February 20, 2024
Received: February 20, 2024

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.

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233901

Device Name

Baby Nasal Aspirator (KA1006, KA1001, KA1005, NASA005, NASA006, NASA008, NASA009)

Indications for Use *(Describe)*

The 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.

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

Prepared on: 2024-03-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Desida Technology Co., Ltd.
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Correspondent Contact Telephone	+86-13418040887
Correspondent Contact	Ms. Youshan Gong
Correspondent Contact Email	youshangong@qq.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Baby Nasal Aspirator (KA1006, KA1001, KA1005, NASA005, NASA006, NASA008, NASA009)
Common Name	Powered suction pump
Classification Name	Pump, Portable, Aspiration (Manual Or Powered)
Regulation Number	878.4780
Product Code	BTA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222547	Electric nasal aspirator	BTA

Device Description Summary

21 CFR 807.92(a)(4)

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.
It consists of main unit, and suction portion working together as one unit. 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.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device and predicate devices have the same indications for use

Technological Comparison 21 CFR 807.92(a)(6)

The vacuum pressure (52 - 60 Kpa) is the same as the predicate device. The power consumption differs from the predicate but the device complies with IEC 60601-1 and IEC 60601-1-2 requirements. The device dimensions (including tip dimensions) and weight are different, but vacuum pressure and flow rate tests were conducted to demonstrate substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

In order to verify and assure the performance of the Baby Nasal Aspirator, we have conducted the product appearance test (color, dimension , weight, etc.), product performance test (vacuum pressure, noise level, flow rate, etc.), and verification on lithium battery power indication.

Not applicable, there is no clinical data.

The subject device and predicate devices have similar indications for use and technological characteristics. The subject device is substantially equivalence to the predicate device, as supported by comparison to the predicate and performance testing outcomes.