May 26, 2026

Shenzhen Root Innovation Technology Co., Ltd.
Rex Hsieh
Regulatory Affairs
#2-201, Floor 2, Hasee Computer Bldg., # 2 Beier Rd.
Bantian St., Longgang District
Shenzhen, 518129
China

Re: K253629
Trade/Device Name: Momcozy Nasal Aspirator (BN007)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA, KMA
Dated: April 26, 2026
Received: April 27, 2026

Dear Rex Hsieh:

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.

Submission Number *(if known)*

K253629

Device Name

Momcozy Nasal Aspirator (BN007)

Indications for Use *(Describe)*

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 function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.

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

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.

1 APPLICANT INFORMATION

Applicant:	Shenzhen Root Innovation Technology Co., Ltd.
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Phone Number:	+886-2-8512-1568 ext.5306
Fax Number:	+886-2-8512-1347
Date prepared:	May 25, 2026

2 SUBJECT DEVICE

Trade/Proprietary Name:	Momcozy
Common Name:	Momcozy Nasal Aspirator BN007
Review Panel:	General & Plastic Surgery
Classification Product Code:	BTA, KMA
Regulation Number:	878.4780
Device Class:	II

3 PREDICATE DEVICE

510(k) Number:	K243138
Trade Name:	Geon (S2) Nasal Aspirator
Manufacturer:	Geon Corporation

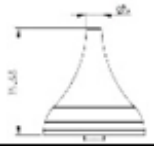
510(k) Number:	K241852
Trade Name:	Nasal Aspirator (NS 13)
Manufacturer:	AViTA Corporation

4 DEVICE DESCRIPTION

Momcozy Nasal Aspirator BN007 consists of a pump that can generate negative pressure suction, a silicone tip for contacting the nostrils, a collection cup for collecting nasal mucus, and a sprayer module including a water tank and a soft silicone sprayer nasal mask that guides the spray mist toward the nostrils to moisturize and soften nasal secretions prior to suction. The device also includes two buttons that activate the suction and sprayer functions.

-Specifications of device.

Property	Specification
Model	BN007
Target Population	Children aged 2–12 years
Use Environment	Home use
Aspiration Tips	Soft silicone (ISO 10993 tested)
Suction Pressure Range	54Kpa~66Kpa (tolerance: 3Kpa)
Spray Capacity	0.24 ml-0.48ml/6sec
Sound Pressure Level	≦60dB
Water Tank Capacity	Approx. 5 mL
Collection Cup Capacity	Approx. 6 mL
Operating Environment	Temperature: 16 °C – 35 °C (60.8 °F – 95 °F) Relative Humidity: 15 % – 85 % (non-condensing)
Storage / Transportation Environment	Temperature: –25 °C – +55 °C (–13 °F – +131 °F) Relative Humidity: 15 % – 85 % (non-condensing)
Battery Capacity	1200 mAh (rechargeable battery, DC 5 V 2 A)
Main Materials	ABS ,PCTG ,silicone, Stain steel, PET
Dimensions	Approx. 77.4 mm (W) × 50 mm (D) × 148.8 mm (H)
Weight	Approx. 200 g

Tip type	Picture	Suggestions for use:	Depth:	Size: OD x D x L (mm)
Gourd shape tip		With a stopper that does not go deep into.	Shallow	Φ5xΦ2.6x35.68 
Long tip		Recommended for use when mucus is thinner.	Deep	Φ5xΦ3x35.68 

5 INDICATIONS FOR USE

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 function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.

6 IDENTIFICATION OF THE PREDICATE DEVICE

NO.	Device Name	Manufacture	Classification and Code	Classification regulation	510K number
Subject Device	Momcozy Nasal Aspirator BN007	AViTA Corporation	Class II BTA, KMA	878.4780	K253629
Predicate Device	Geon (S2) Nasal Aspirator	Geon Corporation	Class II BTA	878.4780	K243138
Predicate Device	Nasal Aspirator (NS 13)	AViTA Corporation	Class II BTA, KMA	878.4780	K241852

7 NON-CLINICAL TESTING

A series of safety, essential performance, and biocompatibility tests were conducted to evaluate the safety and effectiveness of Momcozy Nasal Aspirator BN007 . The tests listed below were conducted in accordance with:

- ISO 10993-1: Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- 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 Sensitization.
- ISO 10993-23: Biological evaluation of medical devices – Part 23: Tests for irritation.
- 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 62304 - Medical device software - Software life-cycle processes
- IEC 62366-1 - Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-6 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral standard: Usability.

The evaluation of suction vacuum and spray capacity were completed during verification testing of the Momcozy BN007 (NS24) Nasal Aspirator. The test results demonstrated that the device passed all performance evaluations. For Model BN007, no measured values exceeded the specified tolerance limits after repeated operation, cleaning, and disinfection cycles. As part of demonstrating acceptable performance of the BN007 Nasal Aspirator in establishing substantial equivalence to the predicate device, the following key functional characteristics were assessed:

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1. Suction Vacuum

BN007 (NS24) Measured Range:

• 54 kPa ~ 66 kPa

• Tolerance: ±3 kPa

Predicate Device:

• Geon S2 Nasal Aspirator (K243138): Claimed suction vacuum range 54 kPa ~ 66 kPa

• AViTA NS13 Nasal Aspirator (K241852): Claimed vacuum pressure 100–120 mmHg

Note: No head-to-head testing of the predicate devices was performed. Substantial equivalence is supported by comparison to the claimed specifications of the cleared predicate devices.

➡ **Comparison Conclusion:**

The suction vacuum of BN007 (54–66 kPa, tolerance ±3 kPa) is identical to the claimed range of the Geon S2 predicate device (K243138). Verification testing demonstrated that BN007 remained within the specified tolerance after repeated operation, cleaning, and disinfection cycles.

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2. Spray Capacity

BN007 (NS24) Measured Value:

- **0.24 mL-0.48mL / 6 seconds**

Predicate Device (AViTA NS13):

- **Comparable spray output (non-clinical performance benchmark)**

(NS13 is used as a performance benchmark due to same device type and same functional operating

principle.)

➡ **Comparison Conclusion:**

The spray capacity of BN007 demonstrates consistent spray output and meets the expected functional performance of a nasal aspirator. Results confirm that BN007 achieves a comparable spray delivery rate to the benchmark device and does not introduce new safety or effectiveness concerns.

Overall Performance Conclusion

The BN007 Nasal Aspirator meets all manufacturer-defined specifications for suction vacuum and spray capacity. The verification data demonstrate that BN007 performs as well as the predicate devices and does not raise new questions of safety or effectiveness.

8 DEVICE COMPARISON TABLE

- **Substantial Equivalence Differences & Justifications (Momcozy BN007)**

Item	Subject (Momcozy Nasal Aspirator BN007) Classification: 21CFR 878.4780 Product Code: BTA, KMA FDA Class II	Predicate (Geon (S2) Nasal Aspirator) Classification: 21CFR 878.4780 Product Code: BTA FDA Class II	**vs. Geon S2 (K243138)**	Predicate ((AViTA Nasal Aspirator NS13) Classification: 21CFR 878.4780 Product Code: BTA, KMA FDA Class II	**vs. NS13 (K241852)**
Intended use	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 function helps moisturize and soften nasal secretions in children (over 3 years old), making them easier to aspirate.	Geon (S2) Nasal Aspirator is a hand-held, non-invasive, electronic medical device that provides negative pressure to remove nasal secretions and mucus from children (age 2–12 years old) at home environment.	**Different**	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.	**Same**
Effective Vacuum Pressure	54kPa~66kPa(tolerance:3kPa)	54kPa~66kPa (tolerance:3kPa)	**Same**	Vacuum Pressure: 100-120 mmHg	**Different**
Sound Pressure Level	≦60dB	55~60dB(tolerance:5dB)	**Different**	≦60dB	**Same**
Spray Capacity	0.24-0.48ml/6sec	N/A	**Different**	0.4~0.5 ml/10sec (2.4~3 ml/min)	**Different**
Operating Temperature Range	16°C ~ 35°C (60.8°F ~ 95°F) 15%~85% RH	15°C ~ 40°C (41°F~104°F) / RH15%~90%	**Different**	16°C ~ 35°C (60.8°F ~ 95°F) 15%~85% RH	**Same**
Storage Temperature Range	- 25°C ~ 55°C (-13°F ~ 131°F) 15%~85% RH	-25°C ~ 55°C (-13°F~158°F) / RH up to 90%	**Different**	- 25°C ~ 55°C (-13°F ~ 131°F) 15%~85% RH	**Same**
Power Requirements	1200mAh,5V2A	2 x 1.5V AAA batteries	**Different**	2 x 1.5V AAA batteries	**Different**
Housing	ABS	ABS	**Same**	ABS	**Same**
Storage pouch	No	No	**Same**	No	**Same**
Unit Weight	Approx.200g (Exclude batteries)	approx.120g (Exclude batteries)	**Different**	Approx.158g (Exclude batteries)	**Different**
Sprayer Nasal Mask	Soft silicone interface that guides spray mist toward nostrils	NA	**Different**	Spray/irrigation nozzle used to deliver moisturizing spray	**Different**

<table>
<tr>
<td>Tips Information</td>
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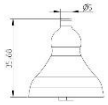
<table>
<tr><th>Tip type</th><th>Picture</th><th>Suggestions for use:</th><th>Depth:</th><th>Size: OD x D x L (mm)</th></tr>
<tr><td>Gourd shape tip</td><td>  </td><td>With a stopper that does not go deep into.</td><td>Shallow</td><td>Φ5xΦ2.6x35.6
 
8</td></tr>
<tr><td>Long tip</td><td>  </td><td>Recommended for use when mucus is thinner.</td><td>Deep</td><td>Φ5xΦ3x35.68
  </td></tr>
</table>
OD: outside diameter / D: diameter

Momcozy Nasal Aspirator BN007 tip type based on the anticipated use. These three types of tips are suitable for children aged 2 to 12 years.
</td>
<td>Different</td>
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 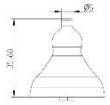
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<td>Same</td>
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- **Difference in Spray Capacity (BN007 vs. AViTA NS13)**

Difference:

- **BN007 spray volume:** 0.24-0.48 ml / 6 sec (2.4-4.8 ml/min)
- **NS13 spray volume:** 0.4–0.5 ml / 10 sec (≈2.4–3 ml/min)

Assessment:
The spray capacity of BN007 partially overlaps with the claimed spray output range of AViTA NS13. Although BN007 has a wider spray output range, both devices provide a spray function intended to moisturize and soften nasal secretions prior to suction.

Justification for SE:
This difference does not impact substantial equivalence because:

1. Both devices use the spray function to support nasal moisturizing, which assists mucus removal.
2. The spray function of BN007 has the same intended functional purpose as the spray/irrigation function of AViTA NS13.
3. The difference in spray output reflects an operational design difference and does not alter the fundamental suction-based operating principle of the device.
4. Verification testing demonstrated that BN007 met its predefined spray capacity acceptance criteria.
5. No new questions of safety or effectiveness are introduced.

➡ **Conclusion:**
The spray capacity difference represents an operational design difference and does not raise new questions of safety or effectiveness.

- **Power Source Difference (Rechargeable vs. AAA Batteries)**

Difference:

- **BN007:** Rechargeable 1200 mAh battery (5V/2A)
- **Geon S2 / NS13:** 2 × AAA batteries

Assessment:
BN007 uses a built-in rechargeable battery, while predicates use replaceable AAA batteries.

Justification for SE:

The change in power source does not affect safety or performance because:

1. Output suction and spray functions are independently verified and within the same range as predicates.

2. Rechargeable power does not alter intended use or raise new EMC risks (EMC fully tested).

3. Device remains non-life-supporting and non-critical; power method does not influence clinical outcome.

➡ **Conclusion:**

This difference is technological but **does not change intended use or introduce new risks**.

Difference in Spray Delivery Interface (BN007 vs. Predicate Devices)

- **Nasal Spray Mask**

Difference:

- BN007 includes a soft silicone sprayer nasal mask that guides the spray mist toward the nostrils.
- The Geon S2 predicate device does not include a spray function.
- The AViTA NS13 predicate device uses a sprayer head/nozzle to deliver moisturizing spray toward the nasal entrance.

Assessment:

The sprayer nasal mask in BN007 functions as a soft silicone interface that guides the spray mist toward the nasal entrance during the spray operation. This component does not independently generate pressure, suction, or aerosol output. Instead, it serves only as a physical interface that directs the spray mist toward the nostrils.

Justification for SE:

The design difference does not impact substantial equivalence because:

1. The sprayer nasal mask performs the same functional role as the spray delivery interface used in the

predicate device NS13.

2. The component only guides the moisturizing spray and does not alter the fundamental operating principle of the device, which is suction-based removal of nasal secretions.

3. The spray function is intended only to moisturize and soften nasal secretions prior to suction and does not introduce new therapeutic functions or additional risks.

➡ **Conclusion:**

The addition of the sprayer nasal mask represents a minor design variation in the spray delivery interface and does not raise new questions of safety or effectiveness.

9 SUBSTANTIAL EQUIVALENCE CONCLUSIONS

The differences between the BN007 and the predicate devices—including suction pressure range (compared with Geon S2), spray capacity (compared with AViTA NS13), power source, device weight, and accessory variations—do not introduce new questions of safety or effectiveness. The fundamental operating principle remains the same: both the subject and predicate devices generate controlled negative pressure to remove nasal secretions in children in a home environment. The additional spray function serves only to moisturize and soften nasal secretions prior to suction and does not alter the clinical purpose of the device. Therefore, the BN007 is substantially equivalent to the identified predicate devices.