December 31, 2024

AViTA Corporation
Maggie Chao
Adm. Manager
9F, No.78, Sec.1, Kwang Fu Road, Sanchong Dist.
New Taipei City, 24158
Taiwan

Re: K241852
Trade/Device Name: Nasal Aspirator (NS13)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA, KMA
Dated: December 2, 2024
Received: December 2, 2024

Dear Maggie Chao:

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)*

K241852

Device Name

Nasal Aspirator (NS13)

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/irrigation function helps moisten and loosen/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.

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

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AVITA CORPORATION

510(k) Submission for

AViTA Nasal Aspirator

510(K) Summary

Applicant:	AViTA Corporation
Address:	9F, No.78, Sec.1, Kwang-Fu Rd., San-Chung District, New Taipei City 24158, Taiwan
Applicant Establishment Number:	9617543
Applicant Contact:	Maggie Chao
Email:	Maggie_chao@avita.com.tw
Phone Number:	+886-2-8512-1568
Fax Number:	+886-2-8512-1347
Date of Submission:	November 28, 2024

DEVICE

Trade/Proprietary Name:	AViTA Nasal Aspirator
Common Name:	Nasal Aspirator
Model:	NS13
Review Panel:	General & Plastic Surgery
Classification Product Code:	BTA KMA
Regulation Number:	870.4780- Powered suction pump
Device Class:	II

DEVICE DESCRIPTION

This AViTA nasal aspirator (Model NS13) consists of a pump that can generate negative pressure suction, a silicone tip for contacting the nostrils, a collection cup for collecting nasal mucus, a sprayer head module for moistening the nasal cavity, and two buttons that activate suction and sprayer functions. This nasal aspirator is powered by two AAA batteries. The accessories are the batteries, silicone tips.

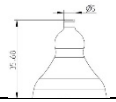
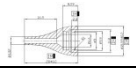
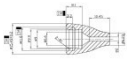
INDICATIONS FOR USE

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.

COMPARISON WITH PREDICATE DEVICE

Item	Subject (AViTA Nasal Aspirator NS13)	Predicate (AViTA Nasal Aspirator NS1 Series)	Predicate (Geonic Nasal Cleaner)
K number	-	K090379	NA
Classification	21CFR 878.4780	21CFR 878.4780	21 CFR 874.5550
Product code	BTA	BTA	KMA
FDA class	II	II	I
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/irrigation function helps moisten and loosen/soften nasal secretions in Children (over 3 years old), making them easier to aspirate.	The device is designed for using intermittent suction to remove nasal secretion and mucus in Children (age 2-12 years old) at home environment.	Geonic Nasal Cleaner (Model Name: H2) additionally provide positive pressure to moisturize the nasal cavities by using saline solution in the form of spray for adults and pediatrics (3 years old). The nasal cleaner is intended for over-the-counter (OTC) use at home environment.
Effective Vacuum Pressure	Vacuum Pressure: 100-120 mmHg	Max.120mmHg	N/A
Optional Levels	N/A	N/A	N/A
Sound Pressure Level	≦60dB	65±3dB	N/A
Spray Capacity	0.4~0.5 ml/10sec (2.4~3 ml/min)	N/A	5 ml/min
Operating Temperature Range	16°C ~ 35°C (60.8°F ~ 95°F) 15%~85% RH	15°C ~ 40°C <95% RH	5°C ~ 40°C (41°F~104°F) RH15%~90% 700-1060pa
Storage Temperature Range	- 25°C ~ 55°C (-13°F ~ 131°F)	- 20°C ~ 50°C <95% RH	-25°C ~ 70°C (-13°F~158°F)

	15%~85% RH										RH up to 90%
Power Requirements	2 x 1.5V AAA batteries					2 x 1.5V AA batteries					3.7 V Li-ion rechargeable battery
Housing	ABS					ABS					ABS
Storage pouch	No					No					No
Unit Weight	Approx.158g (Exclude batteries)					approx.250g (Exclude batteries)					N/A
Tips Information	**Tip type**	**Picture**	**Suggestions for use:**	**Depth:**	**Size: OD x D x L (mm)**	**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	Φ4.02 x Φ2.6 x 28.0	
	Long tip		Recommended for use when mucus is thinner. 	Deep	Φ5xΦ3x35.68	Short tip		Recommended for use when mucus is thick. 	Medium	Φ6.23 x Φ2.0 x 22.2	
	Short tip		Recommended for use when mucus is thick. 	Medium	Φ5.68xΦ3x27.68						
	OD: outside diameter / D: diameter NS13 tip type based on the anticipated use. These three types of tips are suitable for children aged 2 to 12 years.					OD: outside diameter / D: diameter					

Traditional 510(k)

Comparison:

The proposed device and the predicated device have the same principle. There is no additional question of safety and effectiveness as compared to the predicate device.

There is a device currently on the US market that has the same clinical, technical and biological characteristic as the subject device AVITA Nasal Aspirator NS 13.

In Clinical terms, Subject Device and Predicate device have the same intended uses for moistening and clearing nasal congestion and are applicable to the same patient groups, users, and usage environments. In Technical terms, the two have exactly the same working principle and performance specifications. In Biological terms, the parts that contact the human body are exactly the same in terms of materials, process, contact time and contact location.

The following technological differences exist between the subject and predicate devices:

- **About clinical difference (differences in intended use)**
  Regarding the intended use there no difference.
- **About technical difference (differences in Power Supply, Dimensions, Weight, Spray Capacity and Number of Push Button)**
  Regarding the difference in power requirement, the subject device has passed the relevant tests of IEC 60601-1.
  The differences in dimensions, weight, number of push button and spray capacity do not affect the device's safety and effectiveness, as the subject device has passed the relevant tests in accordance with IEC 60601-1-11, and these aspects have been verified through the relevant performance tests.

  In conclusion, the difference in power requirement, dimensions, weight, spray capacity and number of push button do not affect product performance.
  Performance testing has been completed to demonstrate that the Subject device, AVITA Nasal Aspirator NS 13 is substantially equivalent to the Predicate device, AViTA Nasal Aspirator NS 1 Series and Geonic Nasal Cleaner.

PERFORMANCE DATA

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device. The results of those testing show that the required limits for mean difference and standard deviation are fulfilled by the subject device.

Biocompatibility testing

The biocompatibility evaluation and testing of the Product name was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Draft Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing".
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.
- ISO 10993-23, Biological evaluation of medical devices- Part 23: Test for irritation.

Cleaning and Disinfecting Test

The Nasal Aspirator is a medical device that does not supply sterilized. This product has passed the cleaning verification of 1000 times with mild mom-abrasive soap and 70℃ water and soft dry cloth wiping, confirming that the product can be used continuously without any functional abnormalities.

Safety Test:

- IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Basic documentation" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

Clinical Studies

None

CONCLUSION

The substantial equivalence is supported by the results of non-clinical performance testing, labeling and other provided data. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrate that the AViTA Nasal Aspirator NS 13 should perform as intended in the specified use conditions and performs comparably to the predicate device that is currently marketed for the same intended use.