October 20, 2022

Shenzhen XinLianFeng Technology Co., LTD
℅ Reanny Wang
Manager
Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K222547
Trade/Device Name: Electric nasal aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 22, 2022
Received: August 23, 2022

Dear Reanny Wang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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.

510(k) Number *(if known)*
K222547

Device Name
Electric nasal aspirator

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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Traditional 510(k) Summary

510(k) number: K222547

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen XinLianFeng Technology CO.,LTD

Street Address: No.5, Tongxi Road, Pingdong Community, Pingdi Street, Longgang District

City: Shenzhen

State/ Province: Guangdong

Country: China

Telephone: +86-13590244726

Fax: /

Contact Person: Ma Qiang

Contact Title: General Manager

Contact Email: 156673750@qq.com

Date Prepared: Aug. 22, 2022

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1407, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name: Electric nasal aspirator

Model: BC026

Common Name: Powered suction pump

Classification Name: Pump, portable, aspiration (powered)

Regulation: 21 CFR § 878.4780

Device Class: Class 2

Product Code: BTA

3. Identification of Predicate Device(s)

Manufacturer	TaiDoc Technology Corporation	AViTA Corporation
Legally Marketed Device	FORA NAS100 Electronic Nasal Aspirator, NAS100 (Electronic Nasal Aspirator, TD-7601)	Avita Nasal Aspirator, Model NS1
510(K) Number	K180863	K090379

4. Description of Device

Electric nasal aspirator consists of main unit, and 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.

5. 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.

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

6.1 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
- Function test
- Biocompatibility test

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

6.2 Clinical Testing

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

7. Performance Summary

The devices conform to applicable standards as follow table:

Test Type	Standard Designation Number	FDA Recognition Status	Outcome for Device
Safety	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Yes	Conforms
EMC	IEC 60601-1-2:2014	Yes	Conforms
Home healthcare environment	IEC 60601-1-11:2020	Yes	Conforms
Performance	Enterprise standard	Yes	Conforms
Biocompatibility	ISO 10993-1:2018; ISO 10993-10:2010; ISO 10993-5:2009.	Yes	Conforms
Software	IEC 62304:2006+A1:2015	Yes	Conforms
Safety of Lithium battery	IEC 62133-2:2017	Yes	Conforms
Safety of lamps	IEC 62471: 2006	Yes	Conforms
Risk management	ISO 14971:2019	Yes	Conforms

8. Discussion of Comparison to Predicate Devices.

The Electric nasal aspirator submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics, materials, and performance to the cleared FORA NAS100 Electronic Nasal Aspirator **K180863**, and Avita Nasal Aspirator **K090379**. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Device	**Subject device**	**Primary Predicate device**	**Secondary predicate device**	**Comparison**
Manufacturer	Shenzhen XinLianFeng Technology CO.,LTD	TaiDoc Technology Corporation	AViTA Corporation	/
510(K) number	K222547	K180863	K090379	/
Product name	Electric nasal aspirator, model: BC026	FORA NAS100 Electronic Nasal Aspirator, NAS100 (Electronic Nasal Aspirator, TD-7601)	Avita Nasal Aspirator, Model NS1	/
Classification	Class II Device, BTA (21 CFR § 878.4780)	Class II Device, BTA (21 CFR § 878.4780)	Class II Device, (21 CFR § 878.4780)	SE
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	SE
Indication 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 FORA NAS100 Electronic Nasal Aspirator (Electronic Nasal Aspirator, TD-7601), NAS100 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.	This device is designed for using Intermittent suction to remove nasal secretion and mucus in Children (age 2-12 years old) at home environment.	SE
Patient Population	Age 2-12 years old	Age 2-12 years old	Age 2-12 years old	SE
Intended Environment	Home use	Home use	Home use	SE
Device Description	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.	The FORA NAS100 Electronic Nasal Aspirator (Electronic NasalAspirator,TD-7601), NAS100 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.	AVITA NS1 Nasal Aspirator is a portable, DC powered device Intended to provide the suction function to aspirate children's nasal secretion.	SE
Vacuum	52-60Kpa	52-60Kpa	52Kpa	SE

Device	Subject device	Primary Predicate device	Secondary predicate device	Comparison
pressure				
Music function	Yes	Not publicly available	Yes	SE
Light function	Yes	Not publicly available	No	Note 1
Noise Level	＜80dBA	45 dBA	75-80dB/22mm 0.25w/1M	SE
Power consumption	2.2W	3W	Not publicly available	Different Note 2
Motor Type	3.7V DC	3V DC	3V DC	
Power Source	DC 3.7 V / 700mAh Rechargeable Li-ion battery	2x1.5V AA	2x1.5V AA	
Device Dimension	160 (H) x 41 (L) x 41 (W)mm	41 (L) x 41 (W) x 200 (H) mm	93.5(L) x 39.9 (W) x 148(H) mm	Different Note 3
Weight	320±5g	175(g)	250(g)	
Tips Dimension (ψ)	OD4.3/ID2.4	Type1: 5.5 (OD)/ 3(ID) Type2: 4.5 (OD/ 2.5 (ID)	Type1: 6 (OD)/ 2(ID) Type2: 4.2 (OD/ 2.6 (ID)	Similar Note 4
Main Materials	ABS, PC, Silicone	ABS, PC, Silicone	ABS, PC, Silicone	Same
Operating condition	5℃(41℉) to 40℃(104℉); 15% to 93% R.H.	41℉to 104℉; 15% to 93% R.H.	60.8℉ to 95℉; up to 85% R.H.	SE
Storage condition	-10°C(-23℉) to 70°C (158℉) ; 10% to 95% R.H.	-13℉ to 158℉;10% to 95% R.H.	-13℉to 131℉; up to 85% R.H	Similar Note 5
Expected service life	2 years	2 years	Not publicly available	SE
Type BF applied part	Type BF applied part	Type BF applied part	Not publicly available	SE
Safety	IEC 60601-1 IEC 60601-1-11 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1-11	IEC 60601-1	Similar Note 6
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Water‐resistance	IP22	IP22	Not publicly available	SE

Device	Subject device	Primary Predicate device	Secondary predicate device	Comparison
Biocompatibility	BC026 operates in conjunction with silicone nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.	NAS100 (TD-7601) operates in conjunction with silicon nasal aspiration tips, which come into the contact with nasal skin and mucosa for less than 24 hours.	Not publicly available	SE
Standard of Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Not publicly available	SE
Contacted Parts	Silicone Tip (funnel nozzle)	Silicone Tip	Silicone Tip	SE
Material of contacted parts	Silicone	Silicone	Silicone	SE

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

Note 1

The subject device has light function for users to choose. The light of lamp had been verified to comply with IEC 62471, beside, both the predicate devices and subject device are complied with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness.

Note 2

Although the “Power consumption” , “Motor Type” and “Power Source” between the predicate devices and subject device are different, the battery of subject device complied with IEC 62133-2, and both the subject device and predicate devices are all complied with IEC 60601-1. So the difference will not raise safety or effectiveness issue.

Note 3

Although the “Device Dimension” and “Weight” between the predicate devices and subject 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 the subject device is different from that of predicate devices, the Tip’s OD Dimension of subject device is slightly larger than that of (Type 2) secondary predicate device but smaller than that of (Type 2 and type 1) primary predicate device, in general, the OD size is within the range of the predicate devices;

The Tip’s ID Dimension of subject device is larger than that of (Type 1) secondary predicate device but smaller than that of (Type 2 and type 1) primary predicate device, in general, the ID size is within the range of the predicate devices. Beside, both the predicate devices and subject device are complied with the IEC 60601-1and IEC 60601-1-11, so the differences do not affect the safety and effectiveness.

Note 5

The Storage environment of subject 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 safety or effectiveness

issue.

Note 6
Because the Subject device is powered by a lithium battery, the lithium battery needs to meet the requirements of IEC 62133-2, and the subject device has a light function, so its lamp needs to meet the requirements of IEC 62471. In addition, both subject device and predicate devices meet the requirements of IEC 60601-1 and/or IEC 60601-1-11, therefore, the difference will not raise safety or effectiveness issue.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Electric nasal aspirator, model BC026 is substantially equivalent to the predicate devices.