December 19, 2018

TaiDoc Technology Corporation
Sylvia Liu
Regulatory Affairs Specialist
6F, No.127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888 TW

Re: K180863
Trade/Device Name: FORA NAS100 Electronic Nasal Aspirator, Electronic Nasal Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: March 31, 2018
Received: April 2, 2018

Dear Sylvia Liu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180863

Device Name
FORA NAS100 Electronic Nasal Aspirator (Model No: NAS100),
Electronic Nasal Aspirator (Model No: TD-7601)

Indications for Use *(Describe)*
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.

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 summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: **K180863**

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Sylvia Liu
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Prepared Date:	December 10th , 2018

2. Device Name

Proprietary Name:	FORA NAS100 Electronic Nasal Aspirator, NAS100 (Electronic Nasal Aspirator, TD-7601)
Common Name:	Powered Suction Pump
Product Code:	BTA
Review Panel:	General & Plastic Surgery
Device Class:	Class II
Regulation Number:	21 CFR § 878.4780

3. Predicate Device

Proprietary Name:	Avita Nasal Aspirator, Model NS1
Manufacturer	AViTA Corporation
510(K) no.	K090379

4. Device Description

The **FORA NAS100 Electronic Nasal Aspirator (Electronic Nasal Aspirator, 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. Two different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.

Principle of Operation

The **FORA NAS100 Electronic Nasal Aspirator (Electronic Nasal Aspirator, TD-7601), NAS100**, utilizes a motor pump to generate negative pressure in the suction system, which allows nasal secretions to flow into the device container.

5. Indications for Use

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.

6. Technological Characteristics

Table of Specification Comparison

Item	Predicate device	Proposed device
510K Number	**K090379**	**K180863**
General Information		
Appearance		
Device Trade Name / Proprietary name	Avita Nasal Aspirator, Model NS1	FORA NAS100 Electronic Nasal Aspirator (Model No: NAS100); Electronic Nasal Aspirator (Model No: TD-7601)
Manufacturer	AViTA Corporation	TaiDoc Technology Corporation
Common /Classification Name	Powered Suction Pump	**Same as the predicate**
Device Class	II	**Same as the predicate**
Product Code	BTA	**Same as the predicate**
Classification Panel	General & Plastic Surgery	**Same as the predicate**
Regulation Number	21 CFR § 878.4780	**Same as the predicate**

Indication for Use	This device is designed for using Intermittent suction to remove nasal secretion and mucus in Children **(age 2-12 years old)** at **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.
Item	**Predicate device**	**Proposed device**
510K Number	**K090379**	**K180863**
Population	Age 2-12 years old	**Same as the predicate**
Intended Environment	Home use	**Same as the predicate**
Device Description	AVITA NS1 Nasal Aspirator is a portable, DC powered device Intended to provide the suction function to aspirate children's nasal secretion. The device consist of a pump that is driven by Two (2) 1.5V, AA size alkaline batteries, soft aspiration tip, collection cup and Music IC with 12 Chord Melody.	The FORA NAS100 Electronic Nasal Aspirator (Electronic Nasal Aspirator, 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. Two different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.
General Functions		
Vacuum pressure	52Kpa	52-60 Kpa
Noise Level	75-80dB/22mm 0.25w/1M	45 dBA
Power consumption	-	3W
Device Dimension	93.5(L) x 39.9 (W) x 148(H) mm	41 (L) x 41 (W) x 200 (H) mm
Tips Dimension (ψ)	Type1: 6 (OD)/ 2(ID) Type2: 4.2 (OD/ 2.6 (ID)	Type1: 5.5 (OD)/ 3(ID) Type2: 4.5 (OD/ 2.5 (ID)
Weight	250(g)	175(g)
Motor Type	3V DC	**Same as the predicate**
Power Source	2x1.5V AA	**Same as the predicate**
Material	ABS, PC, Silicone	**Same as the predicate**
Operating condition	60.8°F to 95°F; up to 85% R.H. (non condensing)	41°F to 104°F; 15% to 93% R.H. (non condensing)
Storage condition	-13°F to 131°F; up to 85% R.H	-13°F to 158°F;10% to 95% R.H.
Expected service life	-	2 years
Type BF applied part	-	Type BF Applied part
Safety	-	IEC 60601-1

EMC	-	IEC 60601-1-2
Water-resistance	-	IP22
Biocompatibility Information		
Item	**Predicate device**	**Proposed device**
510K Number	**K090379**	**K180863**
Description	Unknown	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. Two different shapes of silicone nasal tips are provided to enable easier and more effective removal of the nasal mucus.
Standard	Unknown	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12
Contacted Parts	Silicone Tip	Same as predicate
Material	-	KE-941U

The conceptual design of the proposed device (**K180863)** is similar to the predicate device (**K090379).** Both have the same principle of operation, general function, and indications for use. The proposed device (**K180863)** has been designed to have smaller dimensions, which makes it more convenient to operate. Another advantage of the proposed device (**K180863)** is a lower noise level, which decreases hearing discomfort during device use.

Additionally, the silicone nasal tips of the proposed device have undergone biocompatibility evaluation. The device complies with general requirements for basic safety and essential performance, and electromagnetic compatibility according to IEC 60601-1-2, IEC60601-11, and IEC 60601-1.

7. Performance Data

Safety and Effectiveness Characteristics:

Standard	Title	Intended Use	Acceptance Criteria	Results
IEC 60601-1	General requirements for basic safety and essential performance	This study is to test for the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their manufacturer for use.	The pass/fail criteria is to evaluate the basic safety and essential performance of medical electrical equipment and medical electrical systems.	1. General requirements, **Pass**. **2.** General requirements for testing ME equipment, **Pass.** **3.** Classification of ME equipment and ME systems, **Pass.** **4.** ME equipment identification, marking and documents, **Pass.** **5.** Protection against excessive temperatures and other hazards, **Pass.** **6.** Accuracy if controls and instruments and protection against hazardous outputs, **Pass.** 7. Construction of ME equipment, **Pass.** **8.** Protection against strangulation or asphyxiation, **Pass.** **9.** Additional requirements for electromagnetic emissions of ME equipment and ME systems, **Pass.** 10. Additional requirements for alarm systems if ME equipment and ME systems, **Pass.**
IEC 60601-1-11	General requirements for basic safety and essential performance – Collateral Standard:	This study is to evaluate to the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their	The pass/fail criteria is to evaluate the basic safety and essential performance of medical electrical equipment and medical electrical systems for	1. General requirements, **Pass**. **2.** General requirements for testing ME equipment, **Pass.** **3.** Classification of ME equipment and ME systems, **Pass.** **4.** ME equipment identification, marking and documents, **Pass.** 5. Protection against excessive temperatures and other hazards,

	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	manufacturer for use in the home healthcare environment, regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel.	use in the home healthcare environment.	**Pass.** **6.** Accuracy if controls and instruments and protection against hazardous outputs, **Pass.** **7.** Construction of ME equipment, **Pass.** **8.** Protection against strangulation or asphyxiation, **Pass.** **9.** Additional requirements for electromagnetic emissions of ME equipment and ME systems, **Pass.** **10.** Additional requirements for alarm systems if ME equipment and ME systems, **Pass.**
IEC 60601-1-2	EMC Test Report	IEC 60601-1-2:2014 applies to the basic safety and essential performance of Medical Equipment (ME) equipment and ME systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by me equipment and me systems.	The pass/fail criteria is limited to maintain the Essential Performance and Basic Safety of EMC requirements.	**1.** Enclosure port, **Pass** **2.** ESD, **Pass** **3.** RS, **Pass** **4.** RF, **Pass** **5.** PFMF, **Pass**
ISO 14971	Risk Management Report	The failure of the function resulting in wrong analytical result which may have serious impairment to the health of a patient may happen. Control measures were taken to reduce the	The risk criteria were established when setting the context, the level of risk would against this criteria in order to determine whether the risk is	The risk distribution is shown the before/after risk analysis to be sure that all hazards are controlled on **"acceptable region".**

		risk to as minimum as possible. Safety and effectiveness of use about the system was then verified.	acceptable.	

Biocompatibility & Clinical Test Report

Standard	Title	Intended Use	Acceptance Criteria	Results
ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Biocompatibility Test Report for Thermometer Biocompatibility Test Report for Stainless Steel Cap Biocompatibility Test Report for Elastic Band Biocompatibility Test Report for Silicon belt	When assessing medical device, the sponsor should specifically state if the medical device does not result in any risk of direct or indirect tissue-contacting components. Thus, performing the biocompatibility test to indicate the safety of device, which includes with Cytotoxicity Test, Skin Sensitization Test, and Irritation Test.	Cytotoxicity Test: If cell viability is reduced to < 70% of the reagent control extract, a cytotoxic potential exists. Skin Sensitization Test: Grades of 1 or greater observed in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. Irritation Test: For each rabbit, the irritation score for test area was calculated by adding together the scores of erythema and edema at each time point and divide the sum by the total number of observation.	1. **Irritation index** for the test result was calculated to be **0.** 2. There were **not found abnormal clinical symptoms except skin reactions in rabbit.** 3. There were normal weight change. 4. The **positive/negative rate** of all sample extract animal is **0%** 5. The sample extract showed **no significant evidence** of causing skin sensitization **in the guinea pig**. 6. Under the conditions of the **MTT assay**, the test article Breast Pump extract **did not show potential toxicity to L-929 cells.**

8. Conclusions

The **FORA NAS100 Electronic Nasal Aspirator (Electronic Nasal Aspirator), NAS100 (TD-7601)** is designed to help users remove the nasal mucus in their children (age 2-12 years old) in a home environment.

The proposed device (**K180863)** has been designed to have smaller dimensions, which makes it more convenient to operate.

Another advantage of the proposed device (K180863) is a lower noise level, which decreases hearing discomfort during the device use.

Also, the **NAS100 (TD-7601)** has been evaluated according to IEC 60601-1-2, IEC60601-11, IEC 60601-1, and ISO 10993. The performance testing demonstrated that the **NAS100 (TD-7601)** is substantially equivalent to the legally marketed predicate device **(K090379)**.