K090379

MAY 2 6 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **AViTA Corporation**

Address: 9F , No. 78 , SEC. 1 , Kwang-Fu Rd., San-Chung, Taipei County, Taiwan , 241

Phone: +886-2-8512-1568

Fax: +886-2-8512-1347

Contact: Mr. Nelson Lin / R&D Manager

2. Device Name :

Trade Name: **AViTA Nasal Aspirator ,**
Model no.: **NS1** Series

Common Name: Nasal Aspirator

Classification name apparatus, suction, ward use, portable, ac-powered

3. DEVICE CLASS The **AViTA Nasal Aspirator, (Model no.: NS1 Series)** has been classified as

Regulatory Class: II
Panel: General & Plastic Surgery
Product Code: JCX
Regulation Number: 21CFR 878.4780 Class II
21CFR 874.5550 Class I

4. Predicate Device: The predicate device is the

- **Aardvark Nasal Irrigation and Aspiration System (K082762)** marketed by **Aardvark Medical Company. .**
- **DeVilbiss SUCTION UNIT(**K982304) marketed by **SUNRISE MEDICAL HHG, ING.**

5. Intended 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.

6. 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.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA Nasal Aspirator, (Model no.: NS1 Series)** has the same intended use and similar technological characteristics as the **Aardvark Nasal Irrigation and Aspiration System (K082762)** marketed by **Aardvark Medical Company**. And **DeVilbiss SUCTION UNIT(**K982304**)** marketed by SUNRISE MEDICAL HHG, ING. . Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **AViTA Nasal Aspirator, (Model no.: NS1 Series)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL -8 2010

Avita Corporation
C/O Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 North Boldt Drive
Flagstaff, Arizona 86001

Re: K090379
Trade/Device Name: Avita Nasal Aspirator, Model NS1
Regulation Number: 21CFR 878.4780
Regulation Name: Powder Suction Pump
Regulatory Class: II
Product Code: JCX
Dated: May 10, 2010
Received: May 21, 2010

Dear Ms. Reich:

This letter corrects our substantially equivalent letter of May 26, 2010

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K090379**

Device Name: **AViTA Nasal Aspirator,**
Model no.: NS1 Series
AViTA Corporation

Indications 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.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
infection Control, Dental Devices

510(k) Number: K090379