K103535

Page 1 of 2

FEB 24 2011

510(k) Summary

[As required by section 807.92(c)]

1. Submitter:
   APEX MEDICAL CORP.
   9, Min Sheng St., Tu-Cheng, Taipei County, 236, Taiwan.

2. Manufacturer:
   APEX MEDICAL CORP.
   9, Min Sheng St., Tu-Cheng, Taipei County, 236, Taiwan.

3. Official Correspondent:
   Alan Chang (Mr.)

4. Date of 510(k) Submittal:
   29/11/2010

5. Device Trade Name:
   VacPlus

6. Common Name:
   Aspirator

7. Classification Name:
   Powered Suction Pump (FDA 21 CFR 878.4780 Class II)

8. Device Product Code:
   JCX

9. Predicate Device:
   DeVilbiss Suction Unit, Model 7305P
   FDA 510(k) number: K982304

10. Device Description:
    VacPlus is the portable AC/DC powered suction unit. Each one consists of an on/off switch, a pump unit, a non detachable flexible power cord, collection jar, relief valve, pressure gauge, pressure adjustment knob, bacteria filter, suction tubing.

11. Intended Use:

The device is to be used to remove fluids from the treated tracheotomy patient airway.

12. Technological Characteristics:

The VacPlus is with aesthetic appeal and meet of today's hygiene and infection control requirements. The VacPlus unit is lightweight, compact and can be used in either AC or DC mode. This unit is available with a rechargeable battery, remote controller.

It has the identical performance characteristics and is equipped with the identical technology like the predicate devices. The technological features do not affect safety and effectiveness of the device or the application.

13. Performance Testing:

Bench testing was performed to support a determination of substantial equivalence and consisted of packaging, electrical safety testing and all testing identified in EN 60601-1, EN 60601-1-2 and EN/ISO 10079-1. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. A risk analysis of the system and its software was performed and testing was conducted to validate the systems overall operations. Biocompatibility testing is not applicable since the proposed device has no direct patient contact.

14. Conclusion:

In terms of intended use, construction, function, safety, operating environmental conditions, and effectiveness of the VacPlus is substantially equivalent to the predicate device used for this application. The VacPlus doesn't with the internal rechargeable portable battery and adopter. There are not significant effecting the safety and effectiveness to our application aspirator.

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

Apex Medical Corp.
% Electronics Testing Center
Hui-chen Kai
No. 8, Lane 29, Wenming Road
Guisan, Taoyuan 33383 Taiwan

FEB 2 4 2011

Re: K103535
Trade/Device Name: VacPlus
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: November 26, 2010
Received: December 01, 2010

Dear Hui-chen Kai:

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. 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); 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

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K 103535

510(k) Number (if known): Not known

Device Name: VacPlus

Indications For Use:
The device is to be used to remove fluids from the treated tracheotomy patient airway.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103535