VEGA TECHNOLOGIES, INC.

510(K) SUMMARY

NOV 1 2 2010

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at October 20, 2010.

The assigned 510(k) number is: K102626 .

1. Submitter's Identifications:
   Establishment:
   DONGGUAN DALANG VIGOR ELECTRONICS MFY.
   Yang Wu District, Da Lang Town, Dong Guan City
   Guang Dong Prov., CHINA
   Registration Number: 9616843
   Operations: Manufacturer

   Owner/Operator:
   VEGA TECHNOLOGIES, INC.
   11F-13, 100 Chang-Chun Rd.,
   Taipei CHINA (Taiwan) 104.
   Owner/Operator Number: 9036509

   Contact: Mr. Joseph Lu
   VEGA TECHNOLOGIES, INC.
   I1F-13, 100 Chang-Chun Rd. Taipei, CHINA (TAIWAN) 104
   Phone: 886-2-2541-6996
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2. Name of the Device:
   VEGA Medical Suction Equipment, model SU-01/SU-DC01.

3. Information of the 510(k) Cleared Device (Predicate Device):
   DeVilbiss Suction Unit (K982304).

4. Device Description:

   The VEGA Medical Suction Equipment, model SU-01/SU-DC01 is a portable AC powered suction pump. It consists of a pump unit, collection bottle, relief valve, vacuum gage, bacteria filter, and suction tube. The device is designed and manufactured to comply with IEC 60601-1, IEC 60601-1-2, and ISO 10079-1.

5. Intended Use:

   The VEGA Medical Suction Equipment, model SU-01/SU-DC01 is a device used to remove fluids from airway or respiratory support system and infectious materials from wounds.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

   The VEGA Medical Suction Equipment, model SU-01/SU-DC01 is substantially equivalent to the DeVilbiss Suction Unit (K982304). The main technological difference made to DeVilbiss Suction Unit (K982304) includes the following four issues:
   1> the operational specification(including vacuum range, flow rate, and collection bottle capacity)
   2> the operational power consumption.
   3> the device outlook, dimensions, and weight.
   4> mode of operation.

7. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of SU-01/SU-DC01 are as the followings:
   1> Performance Compliance Test according to ISO 10079-1 conducted by manufacturer
   2> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
   3> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.

8. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:
   No particular Clinical Test was conducted for VEGA Medical Suction Equipment.

9. Conclusions
   The VEGA Medical Suction Equipment, model SU-01/SU-DC01, has the same intended use and technological characteristics as the cleared device of DeVilbiss Suction Unit (K982304). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

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

Vega Technologies, Inc.
% Mr. Joseph Lu
11F-13, 100 Chang-Chun Road
Taipei, China (Taiwan) 104

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Re: K102626
Trade/Device Name: VEGA Medical Suction Equipment, Model SU-01/SU-DC01
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: November 02, 2010
Received: November 03, 2010

Dear Mr. Lu:

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,

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

Enclosure

VEGA TECHNOLOGIES, INC.

NOV 12 2010

Indications For Use

510(k) Number (if known): K102626 .

Device Name: VEGA Medical Suction Equipment, model SU-01/SU-DC01.

Indications For Use:

The VEGA Medical Suction Equipment, model SU-01/SU-DC01 is a device used to remove fluids from airway or respiratory support system and infectious materials from wounds.

Prescription Use √ 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)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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