K080005

APR 24 2008

510(k) Summary

[As required by section 807.92(c)]

1. Submitter:
   Ding Hwa Co., Ltd
   Rm.4B-02/03, Taipei World Trade Center, 4th Fl., No.5, Hsinyi Rd., Sec.5, Taipei, Taiwan 11011.

2. Manufacturer:
   Ding Hwa Co., Ltd
   No. 43, Hsinkung 1st Road, Peitou Industrial Park, Chang Hua Hsien, Taiwan.

3. Official Correspondent:
   Hui-chen Kai (Ms.)

4. Date of 510(k) Submittal:
   04/12/2007

5. Device Trade Name:
   SPARMAX Aspirator VC-701 and TC-2000V

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 FDA (k)# K982304

10. Device Description:
    SPARMAX Aspirator VC-701 and TC-2000V are the portable AC powered suction pumps. 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:

Similar to the predicate device: In terms of intended use, construction, function, safety, operating environmental conditions, and effectiveness of the SPARMAX aspirator is substantially equivalent to the predicate device used for this application.

Different to the predicate device: The SPARMAX aspirator doesn't with the internal rechargeable portable battery and adopter. There are not significant effecting the safety and effectiveness to our aspirator.

The SPARMAX is with the thermal switch that automatically shuts-off the compressor when it becomes overheated or lack of voltage.

13. Performance Testing:

UL 60601, EN 60601-1-2, UL 1450, and CAN/CSA-C22.2 No.68-92. Refer to the attachment 3 and 4.

14. Conclusion:

In terms of intended use, construction, function, safety, operating environmental conditions, and effectiveness of the SPARMAX aspirator is substantially equivalent to the predicate device used for this application. The SPARMAX aspirator 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
9200 Corporate Boulevard
Rockville MD 20850

Ding Hwa Co., Ltd.
% Electronics Testing Center, Taiwan
Hui-chen Kai
No. 8, Lane 29, Wenming Road
Guishan, Taoyuan 33383
Taiwan

APR 24 2008

Re: K080005
Trade/Device Name: SPARMAX Aspirator VC-701 and TC-2000V
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: March 31, 2008
Received: April 14, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080005

Indications for Use

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

Device Name: SPARMAX Aspirator VC-701 and TC-2000V

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 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) for mkm
Division of General, Restorative,
and Neurological Devices

510(k) Number K080005