NOV - 4 2005

K052650

9.0 510(K) Summary

"510(k) SUMMARY"

9.1	Trade/Proprietary Name:	Pioneer U601 Series Aspirator
9.2	Common/Usual Name:	Aspirator
9.3	Classification Name:	Pump, Portable, Aspiration (Manual or Powered)

9.4 Comparison to Currently Marketed Devices

The Merits Health Products Pioneer U601 Series Aspirator is substantially equivalent to the THOMAS INDUSTRIES MEDI Pump Aspirator Model 1135.

9.5 Device Description

The Merits Pioneer U601 Series Aspirator operates using standard AC Power from a wall outlet. This device consists of a motor-driven oil-less dual piston pump, a vacuum regulation components, a gauge, a bacterial filter and collection system.

9.6 Intended use

The Merits Pioneer U601 Series Aspirator is to be used to remove bodily fluids from the patients' airway or respiratory support system.

9.7 Technological Characteristics

Merits U601 aspirator is equivalent in functions to the legally marketed predicate device. The devices both use an AC motor driven vacuum pump to provide a source of vacuum for suction. The Merits U601 differs from the Thomas 1135 in following characteristics; Merits U601 uses dual piston type pump and has dual fuses for over current protection, Thomas 1135 uses single diaphragm type pump and has no fuse.

9.8 Performance

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

9.9 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits U601 Aspirator is substantially equivalent to the currently marketed device, Thomas Aspirator model 1135.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Mr. Steve Chao
Merits Health Products Company Limited
9, Road 36
Taichung Industrial Park
Taichung,
CHINA (TAIWAN) 407

Re: K052650
Trade/Device Name: Pioneer U601 Series Aspirator
Regulation Number: 21 CFR 868.4780
Regulation Name: Pump, Portable, Aspiration (Manual or Powered)
Regulatory Class: II
Product Code: BTA
Dated: September 20, 2005
Received: September 27, 2005

Dear Mr. Chao:

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.

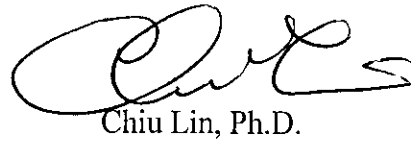
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 STATEMENT

510(k) File Number:

Device Name: Merits Health Products Pioneer U601 Series Aspirator

Indications For Use: The Merits Pioneer U601 Series Aspirator is to be used to remove bodily fluids from the patients' airway or respiratory support system. It is for use on the order of a physician only

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 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)

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

510(k) Number K052650