K041199

JUN - 1 2004

Attachment 5: 510(k) Summary

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Applicant:	Thomas Industries 1419 Illinois Avenue Sheboygan, WI 53082-0029 Telephone: 920.451.0463 Fax: 920.451.4357
Contact Person:	Daniel Pfister, Regulatory Affairs Specialist Telephone: 920.451.4252 Fax: 920.451.4357
Date Prepared:	April 22, 2004
Trade Name:	Medi-Pump Model 1615 Aspirator
Product Classification and Code:	Powered Suction Pump 21 CFR §878.4780 Classification: II Product Code: BTA – Pump, Portable, Aspiration
Predicate Device:	K944399 - Medi-Pump Model 1210 Aspirator
Device Description:	The Medi-Pump is a portable AC powered home use suction pump. The device has been designed, tested and certified to UL 1431. The primary device components include a plastic enclosure, a piston style vacuum pump, a vacuum regulator and gauge, a 1000cc plastic collection jar with overflow valve, an in-line hydrophobic bacterial filter, and a 6' PVC patient tube.
Intended Use:	The Medi-Pump 1615 aspirator is intended to be used to remove bodily fluids from a patient's airway or respiratory system. The aspirator is intended for use in the home by professional home healthcare providers and non-professional caregivers.
Summary of Technological Characteristics:	The model 1615 differs from the predicate model 1210 in the following characteristics; the housing has been modified to provide a more updated, appealing appearance, the device incorporates a slightly different style vacuum pump which provides a slightly higher vacuum, is equipped with a single use (fuse) overload protector and has a non-polarized power plug. Both models have been tested and certified to UL 1431 - Standard for Safety: Personal Hygiene and Health Care Appliances.
Conclusion:	In terms of construction, function, safety and effectiveness the Model 1615 is substantially equivalent to the model 1210 which is also a portable AC powered home use suction pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

Mr. Daniel Pfister
Regulatory Affairs Specialist
Thomas Industries
1419 Illinois Avenue
Sheboygan, Wisconsin 53082-0029

Re: K041199
Trade/Device Name: Medi-Pump Model 1615 Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: April 22, 2004
Received: May 7, 2004

Dear Mr. Pfister:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K04 1199

Device Name: Medi-Pump Model 1615 Aspirator

Indications for Use:

The Medi-Pump 1615 aspirator is intended to be used to remove bodily fluids from a patient's airway or respiratory system. The aspirator is a prescription device intended for use in the home by professional home healthcare providers and non-professional caregivers.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041199