K053490

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 2 4 2006

"510(k) SUMMARY"

9.1 Submitter: Steve Chao
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9.2 Trade/Proprietary Name: Merits Health Products Portable Nebulizer
9.3 Common/Usual Name: Portable Nebulizer
9.4 Classification Name: Nebulizer (direct patient interface)

9.5 Comparison to Currently Marketed Devices

The Merits Health Products Portable Nebulizer consists of compressor and nebulizer. The compressor is substantially equivalent to the currently marketed OMRON HEALTHCARE INC. CompAir Elite (K914836). The nebulizer is equivalent to the currently marketed GaleMed Neb-Easy Nebulizer (K021742).

9.6 Device Description

The Merits Health Products Portable Nebulizer system consists of a DC powered piston-type compressor that generates compressed air. Small, lightweight and designed for convenience, the Merits device offers the user a choice of running off of AC power via a universal adapter or DC power via an option 12 volt auto adapter or an optional rechargeable battery pack. The device consists of a motor driven piston compressor, a printed circuit board and a switch. The circuit board does not incorporate a microprocessor but serves as a means to prevent double feed of power. The circuit board is not a part of the charging circuit for the battery pack.

The nebulizer, which employs a venturi effect to convert the medication into a fine aerosol mist, is used snapped directly onto the compressor outlet. The nebulizer is designed for single patient use, specifically for use only with the Merits compressor. Use different kinds of compressors may impair the performance.

9.7 intended Use

The Merits Health Products Portable Nebulizers are designed to deliver the prescribed liquid medication to treat patients' respiratory disorders, such as asthma, allergies, and bronchitis. The device is not intended for life support nor does it provide any patient monitoring capabilities.

9.8 Technological Characteristics

The Portable Nebulizer operates by using compressor to drive liquid medication via Nebulizer. Compressor type nebulizer had been in use on portable model for many years. Technologies utilized by the portable nebulizer bring forth no new questions of safety and effectiveness. These technologies are well established and have been used in other legally marketed products. There are no major technologies differences between our device and the predicate ones.

9.9 Performance Data

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

9.10 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits Health Products Portable Nebulizers are substantially equivalent to the currently marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2006

Mr. Steve Chao
Merits Health Products Company, Limited
9, Road 36,
Taichung Industrial Park
Taichung, Taiwan R.O.C.

Re: K053490
Trade/Device Name: Merits Health Products Portable Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 15, 2006
Received: July 17, 2006

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

510(k) File Number: K053490

Device Name: Merits Health Products Portable Nebulizer

Indications for Use: The Merits Health Products Portable Nebulizers are designed to deliver the prescribed liquid medication to treat patients' respiratory disorders, such as asthma, allergies, and bronchitis. The device is not intended for life support nor does it provide any patient monitoring capabilities.

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

Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number K053490