9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

**"510(k) SUMMARY"**

JUL - 2 2010

9.1 Submitter:

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9.2 Date of Preparation: April 13, 2010

9.3 Trade/Proprietary Name: Merits Model N Series Nebulizer Compressor

9.4 Common/Usual Name: Nebulizer Compressor

9.5 Classification Name: Portable Air Compressor

9.6 Comparison to Currently Marketed Devices

Both the Merits Model N Series Nebulizer Compressors and the predicate devices are AC-powered, contain the same filter material, meet Environmental, Safety and EMC requirements, and are in the similar compressor operating pressure and flow range. Performance characteristics are basically the same. That is, the Merits Model N Series Nebulizer Compressors are substantially equivalent to the currently marketed SAN UP S.A. Nebulizer Compressor Model: 3050 (K002468).

9.7 Device Description

The Merits Model N Series Nebulizer Compressors consist of AC powered piston-type compressors that generates compressed air. They are small, lightweight and designed for convenience. The piston-type compressor is housed in a plastic cabinet with rubber bumpers. The motor driven piston compressor is connected with a power cord and a switch. The devices contain no microprocessors or other electronic components. They operate from 115VAC/60Hz. Each of them is supplied with tubing, a nebulizer kit and several replaceable filters.

Model N281 and N282 are identical in specifications and components. The only difference is they use different cabinets which are different in size and shape.

When using, the compressor is placed on a flat surface. Air delivery tubing and a nebulizer kit are connected to the outlet hose barb. The air passes the replaceable filter is compressed and delivered to the nebulizer kit through the tubing.

9.8 intended Use

The Merits Model N Series Nebulizer Compressors are AC-powered air compressors intended to provide a source of compressed air for medical purposes for use in home health care. These devices are used in conjunction with pneumatic nebulizers to produce fine aerosol mists of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, etc.

9.9 Technological Characteristics

The Merits Model N Series Nebulizer Compressors operates by using AC-powered motor-driven piston compressor to drive liquid medication via Nebulizer. Compressor type nebulizer has been in use on portable model for many years. Technologies utilized by the Model N Series Nebulizer Compressors 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.

9.10 Performance Data

The Performance & Safety tests performed are summarized in the following.

a. Comparative Performance Test of Merits N281/N282 Nebulizer Compressor & SanUp Model 3050 Compressor
b. IEC/UL 60601-1, Medical Electrical Equipment - Part1: General Requirements for Safety.
c. IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility.
d. Emission of VOCs, CO, O3 & PM2.5
e. Cascade Impaction Testing for Particle Size Analysis

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

9.11 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits Model N Series Nebulizer Compressors are substantially equivalent to the currently marketed 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

JUL - 2 2010

Mr. Steve Chao
Manager
Merits Health Products Company, Limited
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Taichung China
TAIWAN 407

Re: K092859
Trade/Device Name: Merits Model N Series Nebulizer Compressor
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 28, 2010
Received: July 2, 2010

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. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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:

Device Name: Merits Model N Series Nebulizer Compressor

Indications for Use: The Merits Model N Series Nebulizer Compressors are AC-powered air compressors intended to provide a source of compressed air for medical purposes for use in home health care. These devices are used in conjunction with a pneumatic nebulizers to produce fine aerosol mists of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, etc.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K092859