WEINMANN
medical technology

K071163

5. 510(k) Summary

WEINMANN*comfort* 2

April 20, 2007

JUL 18 2007

Submitter Information:

Weinmann
Gerate fur Medizin GmbH+Co. KG
Kronsaalsweg 40
22525 Hamburg / Germany

Submitter's Name:	Eckhardt Albers
Phone:	011 49 40 54 70 2 - 180
Fax:	011 49 40 54 70 2 - 468

Device Name:

Proprietary name:	WEINMANN*comfort* 2
Common Name:	CPAP Device
Classification Name:	Noncontinuous ventilator

Device Classification:

21 CFR 868.5905, Class II, Product Code BZD

Predicate Device Equivalence:

Substantial equivalence is claimed to ResMed S7 Elite CPAP System, cleared for commercial distribution per K013909.

Device Description:

The WEINMANN*comfort* 2 is a microprocessor controlled blower-based device that generates a Continuous Positive Airway Pressure (CPAP) from 4 to 20 cmH_2O for the treatment of Obstructive Sleep Apnea (OSA).

The system includes the flow generator, patient tubing, external power supply, and an optional heated humidifier WEINMANN*aqua*.

A radial compressor draws in ambient air via a filter and conveys it to the unit outlet. From here the air flows through the hose system and the mask to the patient.

The WEINMANN*comfort* 2 has one mode of operation (CPAP fixed-pressure mode). In this mode the flow generator provides a single fixed-pressure as set by the clinician. Automatic

switch on/off can be activated on WEINMANN*comfort* 2. The unit can then be switched on by breathing into the mask and will switch off when the mask is removed. The softstart automatic system is installed to help the patient fall asleep more easily.

The optional breath humidifier WEINMANN*aqua* can be snapped onto the therapy unit. The air from the flow generator is directed over a water surface in the humidifier, which functions according to the pass-over principle.

Intended Use:

The WEINMANN*comfort* 2 is for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The optional integrated humidifier (WEINMANN*aqua*) is indicated for the humidification and warming of air from the WEINMANN*comfort* 2 flow generator device. The WEINMANN*comfort* 2 and WEINMANN*aqua* are for home and hospital use.

Comparison of Technological Characteristics

The WEINMANN*comfort* 2 has the same technological characteristics as the predicate device.

The new device has the following similarities to the previously cleared predicate device:

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

The new device differs in having an external power supply. This change, as well as other minor changes, do not affect safety and effectiveness.

Summary of Device Testing:

Design verification testing was performed to ensure that the WEINMANN*comfort* 2 based on risk analysis and product requirements met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

Conclusion:

Based on the above, we concluded that the WEINMANN*comfort* 2 is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use, and performs as well as or better than the predicate device.

End of section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

Mr. Eckhardt Albers
Quality Assurance Manager
Weinmann Gerate Fur Medizin GmbH + CO. KG
Kronsaalsweg 40
22525 Hamburg,
GERMANY

Re: K071163
Trade/Device Name: WEINMANNcomfort 2, Model WM 27600 and Weinmann Aqua
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 6, 2007
Received: July 11, 2007

Dear Mr. Albers:

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.

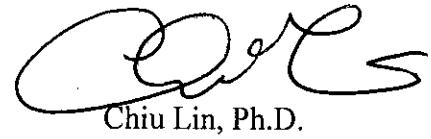
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

4. Indications for Use Statement

510(k) Number (if known): _____

Device Name: WEINMANN*comfort* 2

Indications For Use:

The WEINMANN*comfort* 2 is for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The optional integrated humidifier (WEINMANN*aqua*) is indicated for the humidification and warming of air from the WEINMANN*comfort* 2 flow generator device. The WEINMANN*comfort* 2 and WEINMANN*aqua* are for home and hospital use.

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (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: K071163