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WEINMANN

K022934

510(k) SUMMARY

Weinmann Silentflow 2 Exhalation System

August 27, 2002

Submitter Information:

Gottlieb Weinmann
Geraete für Medizen und
Arbeitsschutz GmbH+Co.
Kronsaalsweg 40
22525 Hamburg Germany

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

Device Name:

Proprietary name: Weinmann Silentflow 2 Exhalation System

Common Name: Exhalation Device

Classification Name: Accessory to non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Respironics Whisper Swivel II Exhalation Port and the MAP Aero-Click®, cleared for commercial distribution per K9622203 and K993094, respectively.

Device Description:

The Weinmann Silentflow 2 Exhalation System consists of two components assembled together. It allows for a patient to exhale during CPAP or bi-level pressure therapy.

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Intended Use:

The Weinmann Silentflow 2 Exhalation System is intended for prescription use to be used with nasal masks which are used in CPAP or bi-level pressure therapy for adult patients (> 30 kg) and do not have a built-in exhalation device.

Comparison of Technological Characteristics:

The Weinmann Silentflow 2 Exhalation System has the same technological characteristics as the predicate devices.

Summary of Device Testing:

Functional and environmental testing was conducted to ensure that the device would perform as described in its specifications

Conclusions:

Based on the above, we concluded that the Weinmann Silentflow 2 Exhalation System is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Eckhardt Albers
Quality Assurance Manager
Gottlieb Weinmann
Geraete für Medizin und Arbeitsschutz GmbH + Co.
Kronsaalsweg 40
22525 Hamburg,
GERMANY

Re: K022934
Trade Name: Weinmann Silentflow 2 Exhalation System
Regulation Number: 868.5905
Regulation Name: Non-continuous Ventilator, Accessory
Regulatory Class: II
Product Code: 73 BZD
Dated: August 27, 2002
Received: September 4, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Runner

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name:

Weinmann Silentflow 2 Exhalation System

Indications for Use:

The Weinmann Silentflow 2 Exhalation System is intended for prescription use to be used with nasal masks which are used in CPAP or bi-level pressure therapy for adult patients (> 30 kg) and do not have a built-in exhalation device.

X Prescription use —OR— ___ Over-the-counter use

William A Noe

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

510(k) Number: K022934