K013738

WEINMANN

JAN 2 2 2002

510(k) SUMMARY

Weinmann SOMNO*mask*

October 31, 2001

Submitter Information:

Gottlieb Weinmann
Geraete für Medizin 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 SOMNO*mask*

Common Name: Nasal mask

Classification Name: Accessory to non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Respironics Reusable Contour II Nasal Mask and to the Puritan-Bennett Breeze SleepGear with DreamSeal, cleared for commercial distribution per K991648 and K002001, respectively.

Device Description:

The Weinmann SOMNO*mask* comes in three sizes, small, medium and large. It has a removable mask seal.

Because the Weinmann SOMNO*mask* does not contain any ports or vents for removing the CO_2 buildup, an external exhalation device must be used.

The SOMNO*mask* is secured to the patient's head with a 4-point headgear called the SOMNO*strap*.

Intended Use:

The Weinmann SOMNO*mask* is intended for prescription use to be used during nasal CPAP or Bi-level Positive Pressure therapy for adult patients (>30 KG).

Comparison of Technological Characteristics:

The Weinmann SOMNO*mask* has the same technological characteristics as the predicate devices.

Summary of Device Testing:

A drop test, operating and storage temperature testing and flow resistance testing were performed to ensure that the SOMNO*mask* met its specifications.

Conclusions:

Based on the above, we concluded that the Weinmann SOMNO*mask* 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

JAN 22 2002

Mr. Eckhardt Albers
Gottlieb Weinmann
Geräte für Medizin und
Arbeitsschutz GmbH + Co.
Kronsaalsweg 40
D-22525 Hamburg, Germany

Re: K013738
Weinmann SOMNOmask
Regulation Number: 868.5905
Regulation Name: Non-continuous ventilator, Accessory
Regulatory Class: Class II (two)
Product Code: BZD
Dated: October 31, 2001
Received: November 13, 2001

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.

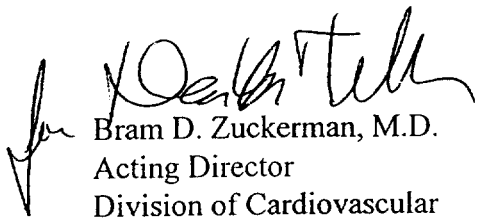
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WEINMANN

Device Name: K013738

Weinmann SOMNO*mask*

Indications for Use:

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Division of Cardiovascular & Respiratory Devices
510(k) Number K013738

Prescription Use ✓
(21 CFR 801.109)