K102515

WEINMANN
medical technology

5. 510(k) Summary

MAR 11 2011

NP15

August 31, 2010

Submitter Information:

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

Submitter's Name:	Dr. Ralf Egenolf
Phone:	011 49 40 54 70 2 370
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Device Name:

Proprietary name:	NP15
Common Name:	Nasal mask
Classification Name:	Accessory to non-continuous ventilator

Device Classification:

21 CFR 868.5905, Class II, Product Code BZD

Predicate Device Equivalence:

Substantial equivalence is claimed to Respironics ComfortLite Nasal Mask, cleared for commercial distribution per K082558. An additional predicate, the Weinmann SOYALA Full Face Mask, cleared for commercial distribution per K061653, is referred to in this submittal as a basis for comparison to certain features, as well as materials other than those used in K082558.

Device Description:

The NP15 is a plastic face mask sealing the patient's nose around the nares and including an exhalation system, for the delivery of CPAP or Bi-level Positive Pressure therapy.

It consists of nasal pillows, mask body, forehead cushion, forehead support, headgear clip, elbow, tube adapter, pressure measurement port with plug, mask tube, rotating sleeve, exhalation system, headgear (including crossband, forehead strap and cheek strap), and tube anchoring clip.

The mask has an integrated exhalation system and provides a swivel and securely attached elbow connection for simple and secure handling of the tubing between the mask and the therapy device.

The NP15 is available as one unit with a set of three different pillow sizes (small, medium, large). It has removable nasal pillows.

The NP15 is secured to the patient´s head with a 4-point headgear.

Intended Use:

The NP15 is intended for

- adult patients (> 30 kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy,
- multiple-patient use in a hospital or clinic environment after high-level disinfection,
- single-patient use in a home environment.

Comparison of Technological Characteristics

The NP15 has the same technological characteristics as the predicate device Respironics ComfortLite Nasal Mask, K082558.

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

- Same intended use
- Same operating principle
- Same technology

Some materials of the new device are different from the predicate device. The changed materials represent secondary support or incidental contact. Safety and effectiveness are not affected by these changes.

Summary of Device Testing:

Bench testing was performed to ensure that the NP15 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 NP15 is substantially equivalent to the legally marketed predicate devices Respironics ComfortLite Nasal Mask, K082558, it is safe and effective for its intended use; and performs as well as or better than the predicate devices.

End of section.

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

Dr. Ralf Egenolf
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GERMANY

MAR 11 2011

Re: K102515
Trade/Device Name: NP15
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 21, 2011
Received: February 28, 2011

Dear Dr. Egenolf:

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,

Anthony 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

WEINMANN
medical technology

4. Indications for Use Statement

510(k) Number (if known):

Device Name: NP15

The NP15 is intended for

- adult patients (> 30 kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy,
- multiple-patient use in a hospital or clinic environment after high-level disinfection,
- single-patient use in a home environment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 and Dental Devices
510(k) Number: K102515