WEINMANN
medical technology

K110984

11. 510(k) Summary

JUL 12 2011

EasyFit SilkGel Nasal Mask

June 07, 2011

Submitter Information:

Weinmann - Geräte fur Medizin GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Germany

Submitter's Name:	Dr. Ralf Egenolf
Phone:	011 49 40 54 70 2 - 370
Fax:	011 49 40 54 70 2 - 468

Device Name:

Proprietary name:	EasyFit SilkGel Nasal Mask
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 SOYALA GEL vented, cleared for commercial distribution per K081014.

Device Description:

The EasyFit SilkGel Nasal Mask is a molded plastic mask, including an exhalation system, for the delivery of CPAP or Bi-level Positive Pressure therapy.

It consists of a mask cushion, mask body, forehead cushion, rough adjustment component, fine adjustment component, headgear, headgear clips, pressure measurement connection, tube anchoring strap, rotating sleeve, elbow, and retaining ring.

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

Intended Use:

The nasal 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 EasyFit SilkGel Nasal Mask has the same technological characteristics as the predicate device.

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

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same mask design

Some materials and mechanical details are changed in the modified device. Safety and effectiveness are not affected by these changes.

Summary of Device Testing:

Biocompatibility testing was performed to verify the equivalent safety of the materials that are used. Bench testing was performed to verify equivalent performance. All tests were verified to meet acceptance criteria.

Conclusion:

Based on the above, we concluded that the EasyFit SilkGel Nasal Mask is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use, and performs as well as the predicate device.

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

JUL 12 2011

Dr. Ralf Egenolf
Head of Quality Management and Regulatory Affairs
Weinmann Gerate Fur Medizin GmbH + Company KG
Kronsaalsweg 40
Hamburg, Germany 22525

Re: K110884
Trade/Device Name: EasyFit SilkGel Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 9, 2011
Received: June 13, 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 D. Watson

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

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6. Indications for Use

510(k) Number (if known): _____

Device Name: EasyFit SilkGel Nasal Mask

Indications for Use:

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

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR 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: K110884