K081743

SEP 2 2 2008

Dräger medical
A Dräger and Siemens Company

510(k) Summary

Summary of Safety and Effectiveness

Applicants Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number: 9611500

Contact Person:

Dr. Karin Luebbers
Senior Manager Regulatory Affairs

Tel. No.: + 49 (451) 882-5367
Fax No.: + 49 (451) 882-7-5367

Applicants US Contact Person

Ms. Joyce Kilroy
VP Processes, Quality & Regulatory Affairs

Tel. No.: (215) 660-2626
Fax No.: (267) 885-9989

Date submission was prepared:

2008-09-09

Device Name:

Trade Name:	**ClassicStar™, NV, Full Face Mask, SE**
Common Name:	Full Face Mask, Noninvasive ventilation
Trade Name:	**NovaStar™, NV, Full Face Mask, SE**
Common Name:	Full Face Mask, Noninvasive ventilation
Trade Name:	**NovaStar™, NV, Full Face Mask, AAV**
Common Name:	Full Face Mask, Noninvasive ventilation

Classification:

Class II

Regulation No.	Device	Product Code
868.5895	Ventilator, continuous, facility use	73CBK

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K023135	Image3 SE Disposable Full Face Mask	Respironics Inc.
K063806	SleepNet MoJo ™ –NV Full Face Mask nonvented	SleepNet Corp.
K060273	SleepNet MoJo ™ Full Face Mask	SleepNet Corp.

Device Description:

Within the medical device family "Noninvasive Ventilation Masks" are devices to provide a patient interface for the application of noninvasive ventilation.

The masks ClassicStar and NovaStar are Full-Face masks which cover the mouth and the nose and are available with a standard elbow (SE) or an anti-asphyxia valve (AAV). Masks with a standard elbow (SE) may only be used on ventilation devices, which incorporate adequate alarm and safety systems for ventilation failure.

A mask with an anti-asphyxia valve (AAV) incorporates the anti-asphyxia valve in the mask elbow.

The ClassicStar Masks are disposable, while the NovaStar Masks are reusable up to 5 times for multiple patients. Further differences are the headgears, which are similar in materials but differ in means of connection to the mask. The headgears are generally provided with the masks, for the reusable masks further headgears are available as optional accessory.

All noninvasive ventilation masks are available in three different sizes (S, M, L).

Intended Use:

ClassicStar™, NV, Full Face Mask, SE (with standard elbow), size S-L:
The mask ClassicStar noninvasive ventilation (NV) with standard elbow (SE) is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. It is intended for use on adult patients (>30 kg/66 lbs), who are appropriate candidates for noninvasive ventilation in the hospital or institutional environment. The mask is disposable and for single patient use.
NovaStar™, NV, Full Face Mask, SE (with standard elbow), size S-L:
The mask NovaStar noninvasive ventilation (NV) with standard elbow (SE) is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2008

Ms. Karin Lübbers
Senior Manger Regulatory Affairs
Draeger Medical AG & Co. KG
53/55 Moislinger Allee
Luebeck
GERMANY 23542

Re: K081743
Trade/Device Name: ClassicStar™, NV, Full Face Mask, SE
NovaStar™, NV, Full Face Mask, SE
NovaStar™, NV, Full Face Mask, AAV
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 10, 2008
Received: September 15, 2008

Dear Ms. Lübbers:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin MD for

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

Indications for Use

510(k) Number (if known): K

Device Name: ClassicStar ™, NV, Full Face Mask, SE
NovaStar ™, NV, Full Face Mask, SE
NovaStar ™, NV, Full Face Mask, AAV

Indications for Use:

The mask ClassicStar noninvasive ventilation (NV) with standard elbow (SE) and the mask NovaStar noninvasive ventilation (NV) with standard elbow (SE) are intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. The masks are intended for use on adult patients (>30 kg/66 lbs), who are appropriate candidates for noninvasive ventilation in the hospital or institutional environment.

The mask ClassicStar NV, with standard elbow is disposable and for single patient use.

The mask NovaStar NV, with standard elbow can be used multiple times on multiple patients. Reuse, however, is limited up to 5 times.

The full face mask NovaStar, noninvasive ventilation (NV), with anti-asphyxia valve (AAV) is intended to be used with positive airway pressure devices, operating at or above 3 mbar (3 cmH2O). The mask contains exhalation ports and does not require the use of a separate exhalation device. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation in the hospital, institutional and in the home environments. The mask can be used multiple times on multiple patients. Reuse, however, is limited up to 5 times.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081743