

19. SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of the safety and effectiveness has been prepared for Nellcor Puritan Bennett *Gemini* Ventilator system in compliance with the Safe Medical Device Act of 1990. The summary of safety and effectiveness is presented on the following pages within this section.

19.1 Manufacturer Name

Nellcor Puritan Bennett Ireland Ltd.
Mervue, Galway, Ireland
Phone: 011-353-91-753771

19.2 Sponsor Name

Nellcor Puritan Bennett Inc.
10200 Valley View Rd.
Eden Prairie, MN 55344
Phone: (612)947-5549

19.3 Proprietary Name of Device

Nellcor Puritan Bennett Inc. *Gemini* Ventilator

19.4 Common Name of Device

Continuous ventilator

19.5 Device Classification

Devices of this generic type have been classified as Class II by the Respiratory Devices Panel. Devices of this type have a classification code of 73CBK regulated under 21 CFR 868.5895.

19.6 Intended Use

The *Gemini* is intended to provide continuous pressure support ventilation to patients requiring respiratory support within a sub-acute care environment. It is intended to be used on adults and children weighing at least 44 lbs (20 kg) for all modes except invasive VTV, which requires a minimum weight of 88 pounds (40 kg). The *Gemini* should not be used by patients requiring device performance outside the published device specifications. For example, some patients (such as those having low compliance or high resistance) will be treated more appropriately with ventilators having the ability to deliver higher pressures.

Gemini is intended to be used in a variety of hospital environments including general hospital floors, emergency rooms, recovery rooms, ICUs and sub-acute environments. It may also be used in hospital-like settings such as sub-acute care centers and nursing homes. It is not intended to be used in home environments or for transport.

Gemini is not intended for delivery of anesthetic gases. Volumes less than 200 ml are contraindicated when using volume ventilation.

19.7 Device Description

The *Gemini* has been designed to target physicians treating patients with moderate respiratory insufficiencies. The *Gemini* provides ventilation modes, alarms and safety features (active exhalation valve) that make it a safer and more effective selection than products carrying an MNS or MNT product code at a fraction of the cost for typical ICU ventilators. Both invasive and non-invasive ventilation are indicated.

The *Gemini* ventilator uses a blower based breath delivery system. The ventilator provides four ventilation modes. These are:

1. Pressure Support Ventilation (PSV)
2. Pressure Support Ventilation with Minimum Respiratory Rate (PSV-MR)
3. Pressure Control Ventilation (PCV)
4. Volume Targeted Ventilation (VTV)

A Volume Priority option can be enabled in both the PSV-MR and PCV modes. *Gemini* also has a proximal exhalation valve in the patient circuit that inhibits rebreathing of air.

The operator communicates with the ventilator through a user interface incorporating three membrane keys, four rotary knobs and an LCD message display window. The LCD display enhances or augments visual/audible display of alarms, settings, modes, menus, and specialized calibration and testing procedures. Safety is enhanced through a software-based settings locking mechanism and the requirement that all changes require a minimum of two actions.

Gemini uses standard domestic (US) 110-115 Vac and European 220-230 Vac power. No battery is available for the device at the time of this submission. Accessories included with the ventilator are:

1. *Gemini* ventilator
2. soft carrying case
3. 6-foot 22 mm hose
4. 6-foot exhalation control tubing
5. 6-foot pressure monitoring tube
6. exhalation valve
7. Operator Manual

8. patient mask and harness (optional)
9. model CM 5000 low/high inspiration pressure alarm (optional)
10. model 7820 oxygen monitor (optional)

19.8 Predicate Device Equivalence

The model TBird VS Ventilation System (K950484) from Bird Products Corp. is the predicate device for the Nellcor Puritan Bennett *Gemini* Ventilator. *Gemini* offers a subset of the TBird's features, modes and indications. Whereas the TBird is indicated for all care conditions requiring mechanical ventilation, the *Gemini* indications are limited to sub-acute care. Both products are intended for institutional environments, but only the TBird claims non-emergency transport use as well. No transport is indicated for the *Gemini*. A more limited patient population is indicated for the *Gemini* as minimum patient weight is specified as 44 pounds (88 pounds for invasive VTV), instead of 22 pounds for the TBird. Also, an ET5 or larger tube is indicated for invasive pediatric use on the *Gemini*. Substantial equivalence to the TBird has been demonstrated through comprehensive specification comparison, and bench and laboratory testing.

19.9 Safety/Hazard Analysis

The *Gemini* hardware, software and functional performance were assessed for safety hazards to both caregiver and patient during normal condition (no fault) and single fault conditions. Label and warning precautions, as well as design techniques, were used to reduce the probability of occurrence or minimize the impact on the patient, or both. The intended use of the device, combined with the hazard/risk analysis results, indicates that the ventilator poses a moderate level of concern.

19.10 Performance Testing

Comprehensive system level functional testing was performed to confirm that the *Gemini* Ventilator meets all stated performance specifications. Performance tests for each of the ventilator critical subsystems were also conducted. It passed all tests.

Electrical, mechanical, environmental and EMC testing was performed to confirm that the *Gemini* Ventilator complies with the November 1993 draft *Reviewer Guidance for Premarket Notification Submissions* published by the Anesthesiology and Respiratory Devices Branch of the Division of Cardiovascular, Respiratory and Neurological Devices. It passed all tests.

All software was tested in compliance with the *Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review* published by the Office of Device Evaluation within the Center for Devices and Radiological Health.

Reliability testing is being performed to estimate the Mean Time Between Failure (MTBF) and Life Testing of the product.

No clinical studies were performed on the *Gemini* Ventilator as safety and effectiveness are confirmed through comprehensive bench testing.

19.11 Conclusion

NPB has concluded that the *Gemini* Ventilator meets its stated performance specifications and the criteria outlined in the FDA's *Reviewer Guidance for Premarket Notification Submissions* dated November 1993 and the *Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*. We conclude that the device will operate safely in its intended environments and will be effective in fulfilling its intended use. Given the intended use and patient criticality level, the *Gemini* features are as safe and effective as the respective features provided on the TBird predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 12 1997

Mr. Chris Hadland
Nellcor Puritan Bennett, Inc.
10200 Valley View Road
Eden Prairie, Minnesota 55344

Re: K972248
Nellcor Puritan Bennett Gemini Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: June 13, 1997
Received: June 16, 1997

Dear Mr. Hadland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Chris Hadland

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

Product Description:

The *Gemini* Ventilator provides continuous pressure support-based ventilation to patients requiring respiratory support. It is capable of providing both patient and machine-triggered breaths utilizing numerous breathing modes. Patient breathing patterns are monitored with both pressure and flow sensors. Breaths are delivered with a blower, driven by an electrically powered motor. Visual and audible alarms sound for various equipment, patient interface and physiologic fault conditions.

Intended Use and Indications:

The *Gemini* Ventilator is intended to provide invasive or non-invasive pressure support ventilation to pediatric and adult patients requiring respiratory support. For invasive and non-invasive pressure ventilation, and non-invasive volume targeted ventilation, the patient should weigh no less than 44 pounds (20 kg). For invasive volume targeted ventilation, the patient should be at least 88 pounds (40 kg). Pediatric restrictions include those patients who require invasive ventilation using an ET4 or smaller diameter tube. The *Gemini* can be used in hospital and hospital-like settings such as the ICU, sub-acute care and nursing home settings. This device is intended to be used on the order, and under the supervision, of a physician.

Concurrence of CDRH, Office of Device Evaluation

510(k) number: K972248

✓ Prescription Use