

510(k) Summary

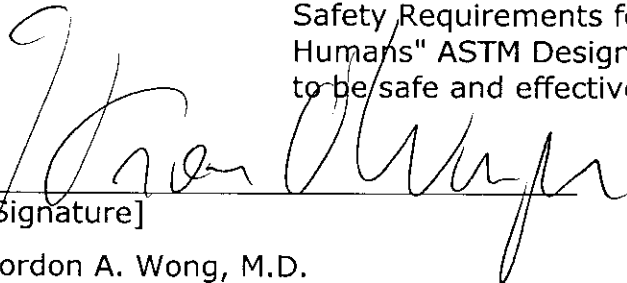
K041473

- 1. Submitter Information: VORTRAN Medical Technology, Inc.
1804 Tribute Road, Suite F, Sacramento, CA 95815
- 2. Contact Information: James Lee, Senior Vice President
TEL: (800) 434-4034 FAX: (916) 648-9751
- 3. Trade Name: VORTRAN Automatic Resuscitator (VAR-Plus™)
- 4. Common Name: Ventilator, Emergency, Powered (Resuscitator)
- 5. Device Class: Class II
- 6. Product code: 73 BTL
- 7. Product classification: per CFR section 868.5925
- 8. Classification panel: Anesthesiology
- 9. Predicate device:

RespirTech PRO	510(k) No.: K973975
RespirTech PRO O ₂ C	510(k) No.: K001430
OXYLATOR™ - EM 100	510(k) No.: K944349
- 10. Device Description: The VORTRAN Automatic Resuscitator (Model VAR-Plus) provides constant flow pressure cycled ventilatory support. The primary working mechanism of the VAR-PLUS is the Modulator which is an exhalation valve that opens at a set PIP (Peak Inspiratory Pressure) pressure and closes at a lower PEEP (Positive End Expiratory Pressure) pressure. During inhalation, exhalation will not start until the peak pressure is reached. During exhalation, inhalation will not begin until the pressure drops to PEEP. The rest of the VAR-PLUS consists of the Patient Connector Tee used to supply a flow of gas, entrain additional air, and provide a redundant pop-off valve
- 11. Intended Use: The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.
- 12. Substantial Equivalency Evaluation: In Vitro Testing per [1] "FDA Draft Emergency Resuscitator Guidance" 14 April 1993 868.5925 Powered Emergency Ventilator (Resuscitator) BTL and [2] "Standard Specification for Minimum Performance and Safety requirements for Resuscitators Intended for Use with Humans", ASTM Designation: F 920 - 93 (Reapproved 1999) An American National Standard.

510(k) Summary

- 13.Operational Characteristics The VAR-PLUS runs on a continuous flow of gas of up to 40 L/min. When connected to a 50 PSIG high flow source, the VAR-PLUS will automatically deliver 40 L/min (667 mL/second). Peak pressure may be adjusted from between 10 and 45 cm H₂O and PEEP is typically 1/5th of PIP. Inspiratory time and rate are adjustable over a wide range. The VAR-PLUS is equipped with an air entrainment valve which allows the patient to entrain additional air and respond to the demands of the patient (pressure support). The VAR-PLUS is also equipped with a redundant pop-off valve that relieves pressure at 60 cm H₂O.
- 14.Clinical Application The VAR-PLUS provides short term, pressure cycled, constant flow ventilatory support using either pressure control or pressure support. In the pressure support mode, the rate dial of the VAR-PLUS is set so that the baseline pressure is above the set PEEP allowing the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. The VAR-PLUS is not an ICU stand alone ventilator with multiple monitoring features. Set up and use of the VAR-PLUS is simple. Set desired flow and adjust pressure dial to obtain desired I-time and/or tidal volume (see tidal volume chart in instructions), and adjust rate dial to obtain desired rate and I to E ratio.
- 15.Clinical Tests None
- 16.Adverse S & E Information None
- 17.Conclusion The VAR-PLUS is substantially equivalent to a predicate device: the RespirTech PRO and Oxylator EM-100. The VAR-PLUS meets the FDA Draft "Emergency Resuscitator Guidance" and the "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans" ASTM Designation: F 920 – 93 and has been shown to be safe and effective.



[Signature]

Gordon A. Wong, M.D.

[Typed Name]

May 27, 2004

[Dated]

President

[Title]



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2004

Mr. James Lee
Senior Vice President
VORTRAN Medical Technology 1, Incorporated
1804 Tribute Road, Suite F
Sacramento, California 95815

Re: K041473
Trade/Device Name: VORTRAN Automatic Resuscitator (VAR-Plus)
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: May 27, 2004
Received: June 2, 2004

Dear Mr. Lee:

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.

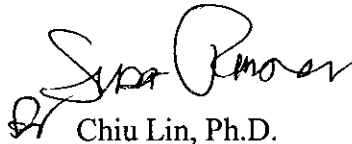
Page 2 – Mr. Lee

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

510(k) Number (if known):

Device Name: VORTRAN Automatic Resuscitator (VAR-Plus)

Indication for Use:

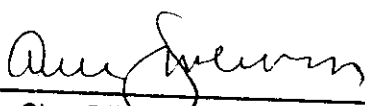
The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

••••• Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use : OR Over-The-Counter Use
(Per 21 CFR 810.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K041473