AUG 2 2 2002

K022402 Section 2 Page 1

Non-Confidential 510(k) Summary of Safety and Effectiveness

July 19, 2002

Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512

Telephone: (973) 790-1330
Fax: (973) 790-7587

Official Contact:	David L. Najjar – Manager of Quality
Proprietary or Trade Name:	Disposable Manometer
Common/Usual Name:	Pressure Manometer
Classification Name:	Airway Pressure Monitor (Per CFR 868.2600)
Device:	Disposable Manometer
Predicate Device:	Engineered Medical System, Inc. – Pressure Manometer – K003497

Device Description:

The VSI disposable pressure manometer is a means of providing visual indication of patient airway pressure during ventilation. The device consists of: A flexible nipple for attachment to a sampling/pressure port, Clear polycarbonate (PC) housing with a printed pressure scale, PC float with indication and a double ended stainless steel spring.

Intended Use:

Indicated Use:

To provide visual indication of a patient's airway pressure during Ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP Mask or CPAP Circuits.

Environment of Use:

Home, Physician Office, Outdoor Environments, Hospital, Sub-acute Institutions, Emergency Services, anywhere airway pressure is measured.

Comparison to Predicate Device:

Attribute	Proposed Device	Engineered Medical System, Inc. K003497
Intended Use	To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP Mask, or CPAP Circuits.	Same
Intended for Single Patient, Multi-Use	Yes	Yes
Prescription	Yes. Labeling will carry: **Caution U.S. Federal Law restricts this device to sale by or on the order of a physician.**	Yes
Intended Population	Any patient requiring airway pressure measurement.	Same
Intended Environment of Use	Home, Hospital, Physician Office, Sub-Acute Institutions, Emergency Services, anywhere airway pressure is measured.	Same
Design Features		
Range of Pressures Measured	0-60 cm H2O	0-60 cm H2O
Can be used on different ventilation devices	It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP Mask, or CPAP Circuits.	Same
Materials		
Polycarbonate, PC	Polycarbonate to be used for manometer body and float.	Same

Contains Latex	No	No
Performance Accuracy cm H2O over the range	**VSI**	Engineered Medical System, Inc.
	+/- 1 cm H2O / 0-10 +/- 2 cm H2O / 10-40 +/- 3 cm H2O / > 40	+/- 1 cm H2O / 0-10 +/- 2 cm H2O / 10-40 +/- 3 cm H2O / > 40

Device Equivalency:

The VSI Disposable Pressure Manometer is viewed as substantially equivalent to the Engineered Medical System, Inc., DPM™, which has been cleared to market under 510(k) K003497.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2002

Mr. David L. Najjar
Manager of Quality
Vital Signs, Incorporated
20 Campus Road
Totowa, New Jersey 07512

Re: K022402
Trade/Device Name: Disposable Pressure Manometer
Regulation Number: 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: July 19, 2002
Received: July 23, 2002

Dear Mr. Najjar:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Patricia Cucciola/for.

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K022402

Device Name: Disposable Pressure Manometer

Indications for Use:

The Disposable Pressure Manometer will be used to provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP Mask or CPAP Circuits.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or Over-the-counter use** _____
(Per CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022402