K102377

NOV 18 2010

A Plus Medical

5.0. 510(k) Summary

Date: August 17, 2010

Owner:

A Plus Medical
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Owner/Operator Number:

10023166

Official Contact:

Thomas C. Loescher
Tel: + 760-930-4025
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Trade Names:

VENT.Plus™ Disposable Pressure Manometer

Common/Usual Name:

Pressure Manometer

Classification Name:

Device Name:	Resuscitator, Manual, Non Self-Inflating
Device Name:	Monitor, Airway Pressure
Product Code:	CAP
Regulation:	CFR 868.2600
Device Class:	II

Device:

VENT.*Plus*™ Disposable Pressure Manometer

Predicate Devices:

Number:	K961318
Product Name:	1st Response Disposable Manometer
Manufacturer:	Smiths Medical (Intertech Resources)
Product Codes:	008201

Number:	K092687
Product Name:	VENT.*Plus*™ Hyperinflation Bag System with Pressure Manometer
Manufacturer:	A Plus Medical
Product Codes:	NA

Device Description:

Single patient use mechanical pressure manometer in which a pressure indicator compresses a spring to a position where the force exerted by the gas equals the force exerted by the compressed spring. Different spring combinations and graduated marking on individual housings allow the device to be offered in 0 – 60 cm H_2O, 0 – 20 cm H_2O and 0 – 15 cm H_2O pressure ranges.

Indications for Use:

Intended for use where monitoring airway pressure is desired by providing a visual indication of airway pressure and may be used on all patient populations in the hospital, pre-hospital, post-hospital and home care environments

Contraindications:

None identified.

Patient Population:

Patient populations of neonate, newborn, pediatric and adult.

Environment of Use:

Hospital, pre-hospital care, post-hospital care and home care.

Comparative of Technological Characteristics:

Testing was performed to document the accuracy of pressure measurement of the predicate and proposed device to an electronic pressure measurement device of ± 0.1 cm H_2O. The A Plus Medical device is substantially equivalent in indications for use, environment of use, patient population, material and function to the identified predicate. Bench testing confirmed that the A Plus Medical device and predicate device have similar performance characteristics and the accuracy of the pressure manometer is equivalent to the predicate under identical test conditions.

Similarities and Differences:

Similarities:

Both are single patient mechanical devices that use a linear spring to which force is applied to measure airway pressure and are of similar construction. Each may be used on all patient populations in the pre-hospital, hospital, post hospital and home care environments where the measuring of airway pressure is desired.

Differences:

The proposed device is offered in three (3) different pressure ranges (0-60 cm H_20, 0-20 cm H_20 and 0-15 cm H_20) while the predicate is offered as a 0-60 cm H_20 device.

Conclusion:

The **vent.***Plus*™ Pressure Manometer is substantially equivalent to the identified predicates.
The **vent.***Plus*™ Pressure Manometer and the identified predicates have substantially equivalent performance.
The **vent.***Plus*™ Pressure Manometer and the identified predicates are made from substantially equivalent material, intended use, patient populations and environment of use.

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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

Mr. Thomas C. Loescher
President
A Plus Medical
5431 Avenida Encinas, Suite G
Carlsbad, California 92008

NOV 18 2010

Re: K102377
Trade/Device Name: VentiPlus™ Disposable Pressure Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: August 20, 2010
Received: August 20, 2010

Dear Mr. Loescher:

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,

for

Anthony 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

A Plus Medical

Indications for Use Statement

K102377

NOV 18 2010

510(k) Number: K102377

Device Name: VENTA-Plus™ Disposable Pressure Manometer

Indications for Use:

Intended for use where monitoring airway pressure is desired. This device provides a visual indication of airway pressure and may be used on all patient populations in the hospital, pre-hospital, post-hospital and home care environments.

Prescription Use X **or** **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K102377