DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 11, 2015

Westmed, Inc.
C/O Paul E. Dryden
Consultant
Pro Medic Inc.,
2430 Woodsage Dr.
Bonita Springs, FL 34134-2958

Re: K143148
Trade/Device Name: Disposable Pressure Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway pressure manometer
Regulatory Class: II
Product Code: CAP
Dated: July 9, 2015
Received: July 13, 2015

Dear Paul E. Dryden:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

We have prepared the Indications for Use statement utilizing Form 3881.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name

Disposable Pressure Manomter (DPM)

Indications for Use *(Describe)*

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.

Patient Population: For patients that the clinician desires to monitor or measure airway or circuit pressure.

Environments for use: Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Date Prepared: 06-Aug-2015

Company Westmed, Inc.
5580 South Nogales Highway
Tucson, AZ 85706

Tel – 520-294-7987
Fax – 520-294-2780

Official Contact: **Diana Upp, Vice President RA / QA**

Proprietary or Trade Name: Disposable Pressure Manometer

Common/Usual Name: Airway Pressure Monitor

Classification Name: 21CFR 868.2600
CAP – Airway Pressure Monitor
Class II

Predicate Device: K003497 – Engineered Medical Systems – Pressure Monitor
Reference Device: K954486 – Mercury Medical – Pressure Monitor
We cite this reference device, as it has the identical indications for use with a pressure range of 0 to 80 cm H_2O.
K040991 – Ambu DPM
We cite this reference device, as it has the identical indications for use with a pressure range of 0 to 60 cm H_2O and the accuracy range consistent with the proposed device.

Device Description:
The Westmed disposable pressure manometer is a means of providing visual indication of patient airway pressure during ventilation.

The device consists of:
1. Clear housing with a printed pressure scale
2. A float with indicator and
3. Spring

It functions by reacting to the positive pressure present in the ventilation device. When pressure is in the device the float moves up or down to indicate the pressure of the system. This manometer displays the pressure in the "circuit". The proposed design incorporates a calibrated spring, which has demonstrated reasonable accuracy over the expected clinical pressure range – 0-60 cm H_2O. The performance characteristics are that the measured pressures are accurate to:

- $\pm$ 3 cm H_2O up to 60 cm H_2O

It is a single patient, disposable, packaged non-sterile device.

Indications for 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.

For patients that the clinician desires to monitor or measure airway or circuit pressure.

Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.

Substantial Equivalence Discussion:
Table 1 compares the key features of the proposed Westmed DPM with the identified predicate and demonstrates that the proposed device is substantially equivalent.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K003497.
Discussion – Each device is indicated for use to measure pressure in a circuit or airway.

Technology and construction –
The design, components, shape, size, etc. are equivalent to the predicates – K003497.
Discussion – The design is simple housing with a float that sits on a spring that goes up or down based upon the pressure in the device. There are markings to indicate the pressure observed as well as a fixed leak to avoid over pressurization. There are no differences in the technological characteristics of the proposed device, predicate and reference devices. The only differences related to the measured pressure ranges: 0-50 cm H_2O for the predicate K003467; 0-80 cm H_2O for the reference K954486; and the proposed which is 0-60 cm H_2O; the accuracy range of the reference K040991. The differences in measured pressure range and accuracy across the pressure range do not raise any new safety or effectiveness concerns.

Environment of Use –
The environments of use are identical to predicate - K003497 – EMS pressure manometer.
Discussion – The environments of use are identical to the predicates - K003497.

Patient Population –
The patient population is defined as patients where the clinician wants to measure or monitor circuit or airway pressure. Therefore there is no specific patient population.
Discussion – The patient populations are equivalent to the predicates - K003497.

Non-Clinical Testing Summary –
We performed a number of tests including comparative pressure accuracy and the results demonstrated equivalent performance demonstrating the proposed device is equivalent to the – K003497 – EMS pressure manometer.

Testing included:

- Accuracy and Repeatability across the full pressure range

- Age testing real-time and simulated to 1 year
- Mechanical testing – Drop test
- Environmental testing
- Positional testing

Summary:

- Accuracy and Repeatability
    - Samples were pressurized across the range and confirmed with the digital manometer
- Aging, Mechanical, Environmental, Positional Orientation, and Accuracy
    - Samples were dropped
    - Samples which had real-time aging and samples in accelerated aging were pressurized to various pressures and confirmed via digital manometer
    - Each sample was tested multiple times

All samples met the pass/fail criteria

- $\pm$ 3 cm H_2O up to 60 cm H_2O

All testing demonstrated that the proposed device is substantially equivalent to the predicate and reference devices.

Biocompatibility

Based upon G95-1 and ISO 10993-1:2009 the proposed device would be considered as having the following patient contact classification:

- External Communication (Indirect contact) for all materials
- Tissue contact
- Limited duration (<24 hours)

We performed the following ISO 10993-1 tests:

- Cytotoxicity; Sensitization; Intracutaneous Reactivity / Irritation

The test requirements were met for the materials to be considered as non-reactive.

Discussion of Differences:

The construction, design, basic materials of the proposed device is similar to the predicate. That is having a housing with a spring and float whereby when pressurized the float moves up or down to indicate the pressure within the system.

The only difference between the proposed device and the predicate is that the maximum displayed pressure is up to 60 cmH_2O vs. 50 cmH_2O. The devices to which these devices are attached can generate higher pressures but their typical operating range can be as high as 80 cmH_2O (reference K954486). The difference in a higher maximum pressure does not raise any new safety and effectiveness issues. It should be noted that the reference device, K040991 Ambu Pressure Monitor has a pressure range up to 60 cm H_2O and the accuracy across the pressure range equivalent to the proposed device.

Substantial Equivalence Conclusion:

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device to be as safe and as effective as predicate and thus can be considered as substantially equivalent.

Table 1 - Comparison to Predicates

Attribute	Predicate EMS – K003497 Pressure Manometer	Proposed Westmed DPM
Indications for 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.	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.
Patient population	Patients that the clinician desires to monitor or measure pressure	Patients that the clinician desires to monitor or measure pressure
Environments of use	Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.	Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.
Prescriptive	Yes	Yes
Single patient use, disposable, non-sterile	Yes	Yes
Connects to a sampling port of any device, i.e. resuscitator, etc.	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.	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.
Basic components	Housing Float Spring Pressure markings Fixed leak in the unit	Housing Float Spring Pressure markings Fixed leak in the unit
Pressure range	0 – 50 cm H_2O Reference K040991 Ambu 60 cm H_2O K954486 Mercury Medical 80 cmH_2O	0 – 60 cm H_2O
Models	Only one	Only one
Performance testing	Accuracy (K003497) • $\pm$ 1 cm H_2O from 0-10 cm H_2O • $\pm$ 2 cm H_2O from 10-40 cm H_2O • $\pm$ 3 cm H_2O above 40 cm H_2O Reference device K040991 • +/- 2 cm H_2O up to 30 cm H_2O • +/- 3 cm H_2O at 40 cm H_2O • +/- 5 cm H_2O at 60 cm H_2O	Accuracy and Repeatability • $\pm$ 3 cm H_2O up to 60 cm H_2O Age Testing – 1 year Drop test
Materials	Polycarbonate Stainless steel	Housing / Float / Cover – Polycarbonate Spring – SUS 304
Biocompatibility		External Communication; Tissue communicating; Limited duration (<24 hours) Tested per ISO 10993-5 and 10993-10