February 24, 2020

Kal-Med LLC
Sandra Greenwood
Office Manager
570 Percival Avenue
Kensington, Connecticut 06037

Re: K191858
Trade/Device Name: Pylant Monitor
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: July 27, 2019
Received: August 16, 2019

Dear Sandra Greenwood:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191858

Device Name
PYLANT MONITOR

Indications for Use *(Describe)*
To provide visual indication of the pressure within an inflatable tracheal tube cuff, which is a device, used to provide an airtight seal between a tracheal tube and a patient's trachea.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5

510(k) Summary
(per 21 CFR 807.92(c))

1. Applicant

Kal-Med, LLC
570 Percival Avenue
Kensington, CT 06037
United States of America

Contact Person:	Sandra Greenwood
Phone:	(585) 633-4225
E-mail:	Sandra@Kalmed.net
Date Prepared:	July 4, 2019

2. Device Name

Trade Name:	PYLANT MONITOR
Common/ Usual Name:	Endotracheal tube (ET) cuff pressure monitor
Classification Name:	Inflatable tracheal tube cuff
Regulation Number:	868.5750
Product Code:	BSK
Device Classification:	II
Review Panel:	Anesthesiology

3. Predicate Devices

The PYLANT MONITOR is substantially equivalent to:

Subject Device	Predicate Device		
	Name	Company	510(k) Number
PYLANT Monitor	PressureEasy	Smiths Medical	K833327

Table 1: Substantial Equivalence Table for PYLANT MONITOR

	Kal-Med	Smiths Medical
Product Name	PYLANT Monitor	PressureEasy
Product Code	BSK	BSK
Regulation No.	868.5750	868.5750
Class	II	II

Company	**Kal-Med**	**Smiths Medical**
Product Name	**PYLANT MONITOR**	**PressureEasy**
Intended Use	To provide visual indication of the pressure within an inflatable tracheal tube cuff, which is a device, used to provide an airtight seal between a tracheal tube and a patient's trachea.	To provide visual indication of the pressure within an inflatable tracheal tube cuff, which is a device, used to provide an airtight seal between a tracheal tube and a patient's trachea.
Basic Principle of Operation	Deflection of an indicator caused by changes in air pressure. This devise has a visual "green" area on the monitor for acceptable pressure range (20-30 cm H_20)	Deflection of an indicator caused by changes in air pressure. This devise has a visual green line appearing for acceptable pressure range (20-30 cm H_20)
Connection type	Connects directly to ETT cuff filling tube. Inflate with syringe.	Connects directly to ETT cuff filling tube. Inflate with syringe.
User Interface	Green accept area on scale	Green dash in window for accept
Accuracy	+/- 4 cm H_20	+/- 4 cm H_20
Materials	Polypropylene	Polypropylene
Intended population	Any patient requiring endotracheal tube cuff pressure measurement	Any patient requiring endotracheal tube cuff pressure measurement

4. Intended Use

To provide visual indication of the pressure within an inflatable tracheal tube cuff, which is a device, used to provide an airtight seal between a tracheal tube and a patient's trachea.

5. Description of the Devices

The PYLANT MONITOR is used by personnel trained in pulmonary resuscitation and airway management (ex. anesthesiologists, RN, respiratory therapists, EMT, paramedics) used to measure the trachael cuff pressure of an endotrachael tube or tracheotomy tube by measuring the external pilot line port of the tube.

The Pylant Monitor (PM) is a medical device intended to indicate changes inside an endotracheal tube (ETT) cuff. One end of the PM is fabricated to fit into the "pilot balloon" (international standard for all types of intra-tracheal tubes with a cuff) of the ETT cuff. The other end is fabricated to accept a medical syringe (international standard for all intravenous syringes) for adding or removing air from inside the ETT cuff and altering the volume of air and therefore the pressure inside the ETT cuff. The syringe end of the PM has a one way air tight valve that is open when the syringe is connected. When the syringe is not connected the valve is closed and air is trapped within the ETT cuff and the PM creating the seal between the trachea and cuff. In between the two ends of the PM is a silicone diaphragm that expands and contacts with pressure. As pressure rises the more the diaphragm expands and as pressure falls the diaphragm contracts. Attached to the center of the diaphragm is and indicator arrow/needle. The diaphragm and arrow/needle is housed inside a designed case. The case acts as a protector of the silicone diaphragm arrow needle assembly and is labeled, color coded and calibrated to indicate pressure ranges from 20 cm H20 to 30 cm H20. The PM is designed to remain connected to the ETT pilot balloon and continuously monitor the pressure or monitor pressure intermittently.

Pressure changes within the ETT when connected to the PM are indicated by expansion or contraction of the silicone diaphragm causing calibrated movement of the arrow/needle and indicated on the color coded label.

6. Summary of Performance Data

Bench tests of the PYLANT MONITOR were conducted comparing PYLANT MONITOR to an FDA cleared pressure monitor; the PressureEasy K833327. The PYLANT MONITOR pressures were substantially equivalent when compared to the PressureEasy Device.

Description of Performance Test

The objective of the testing is to determine if the Pylant Monitor will register the correct ETT cuff pressure. The scale on the monitor has a “set point” which is approximately 25 CM H_20 pressure. The “set point” is the small black line centered in the 20 – 30 mark on the scale. Each Monitor will be pressurized with the PYTON regulator to 25 CM H_20 pressure and will register the pressure from the ETT cuff.

The test consisted of 120 randomly selected production Pylant Monitors. The bench testing included the use of a calibrated Pyton regulator used to pressurize the ETT cuff, which is attached to the Monitor through the inlet tube. Each Monitor was attached to the PYTON pressure regular at the check valve.

In order for the Pylant Monitors to pass, the units must register in the 20 – 30 CM H_20 “safe zone”. When the Monitors were pressurized to 25 CM H_20 pressure all 120 units passed the test by hitting the “mid point” on the scale.

The Pressure Easy devices were tested using the same set-up and test

criteria. This comparative study has been included in Section 18.

7. Safety & Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

Both devices are intended to monitor the pressure inside an ETT cuff. Both devices use a silicone diaphragm that expands and contacts with changes in pressure inside the ETT cuff.

Both devices use a color coded label to indicate pressure changes inside the ETT cuff. Both devices connect to the pilot balloon of an ETT tube and both use a syringe to change volume inside the ETT cuff. Both devices can be left on the pilot balloon for continuous monitoring. The predicate device uses a “plunger” up and down type movement to indicated changes in pressure. The Pylant Monitor uses a “sweep” side to side type movement to indicate changes in pressure. The devices are shaped differently.

It has been shown in this 510(k) submission that the differences between the Pylant Monitor devices and the predicate devices do not raise any questions regarding their safety and effectiveness, and therefore have been determined to be substantially equivalent to the referenced predicate device.