K081805

NOV 1 4 2008

Non-Confidential Summary of Safety and Effectiveness

6-Nov-08

SunMed
12393 Belcher Rd. # 450
Largo, FL 33773

Tel – (727) 530-7099

Official Contact: George Cranton, Director

Proprietary or Trade Name: CuffAlert™

Common/Usual Name: Cuff, tracheal tube, inflatable (accessory)

Classification Name: Cuff, tracheal tube, inflatable (accessory)
BSK – 868.5730

Predicate Devices: Posey Cufflator – K912723
Rusch Endotest – K951046

Device Description:
The CuffAlert™ is a simple in-line pressure monitor which contains a calibrated diaphragm which distends with increases in cuff pressure.

One can set the maximum pressure limit from 10 to 40 cm H_2O by rotating and locking a knob. Once set, it is placed on the pilot balloon connector allowing it to be in-line with the cuff. If the cuff exceeds the set pressure limit on the CuffAlert™ the diaphragm distends making contact with the battery, thus activating the red LED.

The accuracy of pressure measurement has been determined to be +/- 2 cm H_2O @ 10 cm H_2O; +/- 3 cm H_2O @ 20 – 30 cm H_2O; and +/- 4 cm H_2O @ 40 cm H_2O.

Indications for Use: To measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.

The CuffAlert™ is not intended to replacement clinical judgment

Patient Population: Patients who are intubated.

Environment of Use: To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.

Contraindications: None

Attribute	Proposed CuffAlert™	Posey Cufflator™ K912723	Rusch Endotest K951046
Indications for Use	To measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.	Monitor cuff pressure	Monitor cuff pressure
Environments of use	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.	Not specified	Not specified
Patient population	Intubated patients	Intubated patients	Intubated patients
Single patient, disposable	Yes	No	No
Range of measured pressure	10 to 40 cm H_2O	0 to 120 cm H_2O	N/A
Detection of "good range"	LED does not activate	Color coded scale	Color coded scale
Power	Battery operated	Manual	Manual
Accuracy	+/- 2 cm H_2O @ 10 cm H_2O +/- 3 cm H_2O @ 20 – 30 cm H_2O +/- 4 cm H_2O @ 40 cm H_2O	Not specified	Not specified

Differences Between Other Legally Marketed Predicate Devices:
There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2008

SunMed
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K081805
Trade/Device Name: CuffAlert™
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BSK
Dated: November 6, 2008
Received: November 7, 2008

Dear Mr. 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.

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use Statement

510(k) Number: K081805 (To be assigned)

Device Name: CuffAlert™

Indications for Use:

To measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.

The CuffAlert™ is not intended to replacement clinical judgment.

Patients who are intubated.

Environment of Use:

To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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: K081805