510(k) Summary
Page 1 of 3
7-Feb-11

K102704
MAR 10 2011

Joan E. Spiegel, M.D.
10 Coleman Ct.
Natick, MA 01760

Tel – 617-935-3500

Official Contact: Joan Spiegel, M.D.

Proprietary or Trade Name: Easy Cuff™

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

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

Predicate Devices: Posey Cufflator – K912723
SunMed CuffAlert™ - K081805

Device Description: The Easy Cuff™ is simple in-line pressures monitor which contains a calibrated diaphragm which distends with increases in cuff pressure. It is also capable of inflating or deflating the cuff.

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

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 Easy Cuff™	Posey Cufflator™ - K912723	SunMed CuffAlert - K081805
Indications for Use	To inflate cuffs and to measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.	To inflate, measure and monitor cuff pressure	To measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.
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 but the same	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.
Patient population	Intubated patients	Intubated patients	Intubated patients
Single patient, disposable	Yes	No	Yes
Range of measured pressure	0 to 30 cm H_2O	0 to 120 cm H_2O	10 to 40 cm H_2O
Detection of "good range"	Color coded scale	Color coded scale	LED does not activate
Power	Manual	Manual	Battery operated
Accuracy	+/- 5% up to 30 cmH_2O +/- 0.5 cm H_2O @ 10 cm H_2O +/- 1 cm H_2O @ 20 cm H_2O +/- 1.5 cm H_2O @ 30 cm H_2O	Not specified	+/- 2 cmH_2O @ 10 cmH_2O +/- 3 cmH_2O @ 20-30 cmH_2O +/- 4 cmH_2O @ 40 cmH_2O
Performance Testing	Inter-sample and Intra-sample testing for accuracy and repeatability across the pressure range Tested for accuracy at different temperatures and after drop test	Not specified	Accuracy across the pressure range Tested for accuracy at different temperatures Drop test

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.

The Easy Cuff™ is viewed as substantially equivalent to the predicate devices because:

Indications –
The Easy Cuff™ is intended to allow one to inflate the cuff, measure and monitor the pressure in the cuff. This is identical to the predicates –

Posey Cufflator – K912723 – inflates, measures and monitors pressure

SunMed CuffAlert – K081805 – measures and monitors cuff pressure only it does not have an active component to inflate the cuff

Technology –
The Easy Cuff™ uses a diaphragm / bellows which moves in relationship to the measured pressure. This nearly identical to the predicate SunMed which uses a diaphragm to measure pressure and the deflection of the diaphragm will activate the LED sensor – SunMed CuffAlert – K081805.

Materials –
There are no materials in the gas and fluid pathway.

Environment of Use –
The environment of use is wherever one would want to measure cuff pressure, which is identical to predicate – Posey Cufflator – K912723 and SunMed CuffAlert – K081805

Patient Population –
Population is defined not by age but by those that have an airway which has a cuff which needs to be inflated / deflated, and the pressure measured and monitored.

This is identical to predicate – Posey Cufflator – K912723 and SunMed CuffAlert – K081805

Performance Testing –
We performed equivalent bench testing, including accuracy, high and low temperature and drop testing and the Easy Cuff™ performed as intended and its accuracy is substantially equivalent to the SunMed Cuff Alert (K081805).

These tests were equivalent to the testing required of the predicates.

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

Joan Spiegel, MD
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodstage Drive
Bonita Springs, Florida 34134

MAR 10 2011

Re: K102704
Trade/Device Name: Easy Cuff™
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BSK
Dated: February 7, 2011
Received: February 8, 2011

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. 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,

Anthony D. 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

Indications for Use Statement

510(k) Number: K102704 (To be assigned)

Device Name: Easy Cuff™

Indications for Use:

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

Patient population:

Patient 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

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