

510(k) Summary

K092733

1. **Official Contact Information:**
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2. **Proprietary or Trade Name:** PYTON
3. **Common / Usual Name:** ETT Cuff Pressure Regulator
4. **Classification Name:** Cuff, Tracheal Tube, Inflatable
5. **Regulation Number:** 21 CFR 868.5750
6. **Classification Product Code:** BSK
7. **Predicate Devices:**
 - 7.1. Cuff Mate 2 Endotracheal Cuff Inflator and Monitor,
 - 7.1.1. Manufacturer: Diemolding Corporation
 - 7.1.2. FDA 510k number: K902114
 - 7.1.3. Classification Product Code: BSK
 - 7.2. Posey Cufflator
 - 7.2.1. Manufacturer: Posey Co.
 - 7.2.2. FDA 510k number: K912723
 - 7.2.3. Classification Product Code: BSK
 - 7.3. Rusch Endotest Cuff Pressure Monitor
 - 7.3.1. Manufacturer: Rusch Intl.
 - 7.3.2. FDA 510k number: K951046
 - 7.3.3. Classification Product Code: BSK
 - 7.4. PressureEasy Cuff Pressure Controller
 - 7.4.1. Manufacturer: Smiths Healthcare Manufacturing
 - 7.4.2. FDA 510k number: K833327 (There have been several companies that have marketed this device over the years since it first was approved.)
 - 7.4.3. Classification Product Code: BSK
 - 7.5. Model GV-10 Lanz Pressure Valve
 - 7.5.1. Manufacturer: Extracorporeal Medical Specialties, Inc.
 - 7.5.2. FDA 510k number: K791045
 - 7.5.3. Classification Product Code: BTR
 - 7.6. CuffAlert
 - 7.6.1. Manufacturer: SunMed
 - 7.6.2. FDA 510k number K081805
 - 7.6.3. Classification Product Code: BSK

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8. **Functional Summary of the PYTON:** The PYTON measures the ETT cuff pressure, and automatically adjusts the air pressure inside the ETT Cuff to a level selected by the user who is intended to be a professional respiratory practitioner. Room air is the “fluid” that is utilized to inflate the ETT Cuff, so there is not any use of (or contact to) any of the patient’s biological fluids by the PYTON.
- 8.1. **Monitoring Function:** The monitoring function is achieved by use of a pressure sensor.
- 8.2. **ETT Cuff Pressure Regulation:** The automatic ETT cuff pressure regulation is achieved by activation of either a small air pump (of the same type used in many automatic blood pressure cuff measurement systems) in order to raise the ETT cuff pressure, or by activation of a “dump” valve to lower the ETT cuff pressure.
- 8.3. **User Interface:** The PYTON provides an LED back-lit LCD digital display to report the ETT cuff pressures to the user, and four pushbuttons that provide the user with the ability to select the target ETT cuff pressure, and check battery charge level.
- 8.4. **Safety Valve:** The PYTON includes a mechanical pressure relief valve as a safety precaution that ensures a maximum ETT cuff pressure (in the case of a PYTON failure) to a level of 1.5 p.s.i. (105 cmH₂O) +/-20%.
- 8.5. **Battery Back-Up:** The PYTON includes a battery back-up power supply allowing the PYTON to be used for up to 10 hours without mains power. This feature allows (as most of the predicates do) for the PYTON to be used while the patient is moved within the hospital to X-Ray for example, or during transport of the patient.
9. **Intended Use:**
- 9.1. To measure, and regulate intra-cuff pressures of endotracheal, supraglottic airways, and tracheostomy tubes.
- 9.2. The PYTON is intended for use on patients who are intubated.
- 9.3. The PYTON is to be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics where a patient may be intubated.
10. **Prescription Use:** Caution: US Federal law restricts this device to sale by or on the order of a physician.
11. **Steps in the Application of the PYTON:** The intended use instructions for respiratory practitioners are briefly summarized below:
- 11.1.1. **Connection of the PYTON to the ETT Cuff Pilot Balloon:** The PYTON connects through a plastic tubing set to the ETT Cuff pilot balloon connector with a male Luer adapter exactly like predicate devices.
- 11.1.2. **Set Cuff Pressure:** The respiratory practitioner next powers on the PYTON device and selects the target ETT Cuff pressure with a few key strokes on the PYTON’s front panel. Generally accepted ETT cuff pressure levels for high volume/low pressure cuffs are in the range of 20 to 30 cmH₂O. The PYTON includes a default “SET” cuff pressure value of 25 cmH₂O.
- 11.1.3. **Monitor/Regulation:** The PYTON automatically adjusts the ETT Cuff pressure to the target “SET” point pressure, and continues to monitor, and adjust the cuff pressure to the “SET” point pressure.

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12. Summary of Technological Characteristics of the PYTON ETT Cuff Pressure Regulator as Compared to Predicate Devices: The PYTON ETT Cuff Pressure Regulator performs two functions. It monitors the ETT Cuff Pressure, and secondly, it regulates the ETT cuff pressure to a "SET" point pressure within +/- 2 cmH₂O. All the predicate devices perform the monitoring function, and some also provide pressure regulation, as well. A brief discussion of these points is given below.

12.1. The automatic pressure regulation found in the predicate devices listed above like the PressureEasy Cuff Pressure Controller, and the Model GV-10 Lanz Pressure valve are equivalent to the PYTON's pressure regulation.

12.2. The PYTON's monitoring function is equivalent to the monitoring functions of all the predicate devices listed above. The PYTON is electrically powered as is the CuffAlert and the Cuff Mate 2 Endotracheal Cuff Inflator, and Monitor. Both the PYTON and the Cuff Mate 2 incorporate LCD digital displays of the ETT cuff pressure in units of "xx" cmH₂O. The Cuff Mate 2, however, does not employ automatic pressure regulation as found in the PYTON.

12.3. The CuffAlert device is also electrically powered, and it is similar in its monitoring function to the PYTON in that it incorporates and monitoring device that alerts the user by illuminating a red LED if the tracheal cuff pressure is too high.

12.4. **Determination of Substantial Equivalence:** (See Table 1)

12.4.1. The monitoring mode of the PYTON is similar to each of the predicate devices.

12.4.2. The pressure regulation feature of the PYTON is similar to the following predicate devices:

12.4.2.1. The PressureEasy Cuff Pressure Controller

12.4.2.2. The Model GV-10 Lanz Pressure Valve

12.4.3. The PYTON has the same intended use as each of the predicate devices. (Allowing for manual regulation of the Cuff Pressures by some of the predicate devices.)

12.4.4. The PYTON has the same intended patient population and use environments that each of the predicate devices have.

12.4.5. The PYTON does not raise new questions as to the safety and effectiveness of cuff pressure regulator devices.

12.4.6. The PYTON has similar instructional information, including warning and caution statements as compared to the predicate devices.

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Table 1: Non-Confidential Summary of Safety and Effectiveness

Attributes/Description	PYTON (Proposed Device)	Cuff Mate 2	CuffAlert	Posey Cufflator and Rusch Endotest	PressureEasy and Model GV-10 Lanz Pressure Valve
FDA 510k number	To be assigned	K902114	K081805	K912723- Posey K951046- Rusch	K833327 - PressureEasy K791045-GV-10 Lanz Pressure Valve
Indications for use	To measure and regulate intra-cuff pressures of endotracheal, supraglottic airways, and tracheostomy tubes	Same, except that regulation is performed manually.	Same, except that regulation is performed manually.	Same, except that regulation is performed manually.	To measure and regulate intra-cuff pressures of oral/nasal endotracheal tubes.
Environments of Use	To be used under medical supervision in hospitals, pre-hospitals (EMS), extended care facilities and outpatient clinics where a patient may be intubated.	(Same)	(Same)	(Same)	(Same)
Patient Population	Intubated patients	(Same)	(Same)	(Same)	(Same)
Single Patient or Reusable?	Reusable	(Same)	(Same)	(Same)	Single-patient
Range of measured Cuff Pressure	0 to 85 cmH2O	0 to 99 cmH2O	10 to 40 cmH2O	0 to 120 cmH2O- Posey 0 to 120 cmH2O - Rusch	20-30 cmH2O – PressureEasy 30 to 34 cmH2O – GV-10 Lanz Pressure Valve.

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Accuracy of Cuff Pressure Measurement	+/-1 cmH2O (see Bench Tests for validation.)	+/- 2.4 cmH2O (2 Std Dev from study done in Feb 2004)	+/- 3 cmH2O @ Cuff Pressures 20 to 30 cmH2O	+/- 3.8 cmH2O- Posey +/- 2.6 cmH2O- Rusch (2 Std Dev from study done in Feb 2004)	Not Specified
Power	Battery or Wall Cube supply	Battery	Battery	Manual	Manual

12.5. Summary of Performance Testing:

- 12.5.1. Electrical safety testing was conducted per EN 60601-1.
- 12.5.2. EMC testing was performed per EN60601-1-2.
- 12.5.3. Software validation testing was performed per FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices.
- 12.5.4. Electrical, mechanical and environmental testing of the PYTON was conducted in accordance with the FDA Draft Reviewer Guidance for Premarket Notification Submissions (1993).
- 12.5.5. Conclusion: The results of all performance tests demonstrate that the PYTON meets its design and system requirements.

13. Conclusions: The technological characteristics of the PYTON ETT Cuff Pressure Regulator and the results of bench tests do not raise new questions of safety or effectiveness when compared to the legally marketed predicate devices.



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

Anthony Calderoni
President
ARM Medical Devices, Incorporated
190 Dino Road
Bristol, Connecticut 06010

FEB 26 2010

Re: K092733
Trade/Device Name: PYTON
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: February 22, 2010
Received: February 24, 2010

Dear Mr. Calderoni:

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.

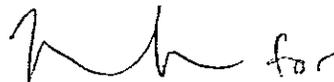
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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: K092733 (To be assigned)

Device Name: PYTON

Indications for Use:

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

The PYTON is intended for use on patients who are intubated.

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

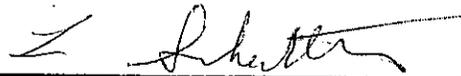
Prescription Use: YES or **Over-the-Counter Use:** NO

(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

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