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

May 8, 2015

Teleflex Medical
c/o Mr. Paul Dryden
Consultant
3015 Carrington Mill Blvd.
Morrisville, NC 27560

Re: K142103
Trade/Device Name: Cuff Pilot™, SureSeal™ with Cuff Pilot™
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK, CAE
Dated: April 27, 2015
Received: April 28, 2015

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 contact 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. 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,

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142103

Device Name

Cuff Pilot™

Indications for Use *(Describe)*

To monitor intra-cuff pressures of supraglottic airways.

Patient Population:
Patients who have an artificial airway and for which the user would like to monitor cuff pressure, pediatric to adult.

Environments of Use:
To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may have an artificial airway. It may also be used in MRI suites when attached to airways that are MR conditional or MR Safe.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number *(if known)*

K142103

Device Name

SureSeal™ with Cuff Pilot™

Indications for Use *(Describe)*

The SureSeal™ supraglottic airway with attached Cuff Pilot ™ is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients and emergency procedures using either spontaneous or Positive Pressure Ventilation (PPV).

- An alternative to a face mask.
- An airway device in routine anesthesia procedures.
- Securing the immediate airway in anticipated or unexpected difficult airway situations.
- Use in elective surgical procedures where tracheal intubation is not necessary.
- Establishing an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient requiring artificial ventilation when tracheal intubation is not possible.

Patient Population:
Patients who need an artificial airway, pediatric to adult.

Environments of Use:
To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient needs an artificial airway. It may also be used in MRI suites and is considered MRI Safe.

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)

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510(k) Summary

8-May-15

Teleflex Medical
3015 Carrington Mill Blvd Telephone: 919-361-3934
Morrisville, NC 27560 Fax: 919-433-4996

Official Contact: Justin Lovelace
Regulatory Affairs Specialist

Proprietary or Trade Name: Cuff Pilot™

Common/Usual Name: Cuff Pilot™
SureSeal™ with Cuff Pilot™

Classification Name: Cuff, tracheal tube, inflatable (accessory)
BSK – 21 CFR 868.5750, Class II
Airway, oropharyngeal
CAE – 21 CFR 868.5110, Class I

Predicate Devices: Easy Cuff – K102704
LMA™ Classic – K130304

Device Description:
The Cuff Pilot™ is a simple device which allows the user to monitor the cuff pressure of supraglottic airways. It has been designed to display pressure ranges via color coded zones. The Cuff Pilot™ is designed with an internal bellows, is compressed as pressure increases and expands when intra-cuff pressure is less. There is an O-ring indicator that is on the bellows and this indicates the status of pressure within the define color coded pressure zones.

The SureSeal™ supraglottic airway is very similar in design, performance, indications for use, technology of operation, and materials to our LMA airways. It will have the Cuff Pilot™ attached and is considered MR Safe.

Indications for Use - Cuff Pilot™
To monitor intra-cuff pressures of supraglottic airways.

Patient Population: Patients who have an artificial airway and for which the user would like to monitor cuff pressure, pediatric to adult.

Environments of Use: To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may have an artificial airway. It may also be used in MRI suites when attached to airways that are MR conditional or MR Safe.

Indications for Use – SureSeal™ with Cuff Pilot™
The SureSeal™ supraglottic airway with attached Cuff Pilot™ is indicated for use in achieving and

maintaining control of the airway during routine anesthetic procedures on fasted patients and emergency procedures using either spontaneous or Positive Pressure Ventilation (PPV).

- An alternative to a face mask.
- An airway device in routine anesthesia procedures.
- Securing the immediate airway in anticipated or unexpected difficult airway situations.
- Use in elective surgical procedures where tracheal intubation is not necessary.
- Establishing an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient requiring artificial ventilation when tracheal intubation is not possible.

Patient Population: Patients who need an artificial airway

Environments of Use: To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient needs an artificial airway. It may also be used in MRI suites and is considered MRI Safe.

Attribute	**Predicate** **Easy Cuff (K102704)**	**Proposed Device** **Cuff Pilot™**
Indications for Use	To inflate cuffs and to measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.	To monitor intra-cuff pressures of supraglottic airways.
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.	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may have an artificial airway. It may also be used in MRI suites when attached to airways that are MR conditional or MR Safe.
Patient population	Intubated patients	Patients who have an artificial airway and for which the user would like to monitor cuff pressure, pediatric to adult.
Technology	Bellows that move with changes in pressure Expands with higher pressures Contracts with lower pressures	Bellows that move with changes in pressure Contracts with higher pressures Expands with lower pressures
Method of inflating cuff	Use the integrated syringe Manual	Use an independent syringe (normal practice) Manual
Attaches to the Cuff Inflation Pilot	Yes via a luer fitting	Yes via a luer fitting May be permanently attached to an airway's cuff inflation line
Types of airways to which it can be used	Supraglottic airway Endotracheal tube Tracheostomy tube	Supraglottic airway
Single patient, disposable	Yes	Yes
Pressure Range of the device	0 to 60 cm H_2O	0 to 80 cm H_2O

Attribute	**Predicate** **Easy Cuff (K102704)**	**Proposed Device** **Cuff Pilot™**
Detection of "good range"	Color coded and a scale	Color coded zones
Packaged	Non-sterile	Non-sterile Sterile
Accuracy	+/- 1 cmH_2O up to 30 cmH_2O +/- 2 cmH_2O at 40 cmH_2O +/- 5 cmH_2O at 60 cmH_2O	+/- 5 cmH_2O up to 80 cmH_2O
MRI Use	Not labeled	MR Safe based upon the lack of materials which contain metal or are magnetic per ASTM F2052-06, rationale
Shelf-life	Not provided	3 years
Performance Testing	Accuracy across the pressure range Repeatability Tested for accuracy after exposure to high and low temperatures Drop test	Accuracy within the pressure zone ranges Repeatability Subjected samples to aging and exposure to cold and hot temperatures Drop / Shipping test

Substantial Equivalence Discussion:
The Cuff Pilot™ is viewed as substantially equivalent to the predicate devices because:

Indications –
The Cuff Pilot™ is intended to monitor the intra-cuff pressure of Supraglottic airways.
Discussion – The predicate, EasyCuff™ (K102704) is designed to inflate the cuff instead of requiring a separate syringe, which is the normal practice. This difference does not raise any new safety or effectiveness concerns, thus the proposed device is considered substantially equivalent. The proposed Cuff Pilot™ is intended to monitor changes in cuff pressure and display the pressure within a range or zone. Actual pressure will be set or checked with a separate cuff pressure gauge.

Environment of Use –
The Cuff Pilot™ has the same environment of use as the predicate plus MRI suites.
Discussion – The Cuff Pilot™ has no magnetic materials and thus can be considered MR Safe. It can be used with any artificial airway that is deemed to be MR Conditional or MR Safe. The predicate is likely MR Conditional but it was not an indication in the original submission. This difference does not raise any new safety or effectiveness concerns that have not been addressed in the rationale and thus the proposed device can be considered substantially equivalent.

Patient Population –
The Cuff Pilot™ has the same patient population as the predicate.
Discussion – Since patients who have a supraglottic airway are not technically considered "intubated"; the predicate, EasyCuff™ (K102704) term in not correct. This is no different than the predicate and thus the proposed device is considered substantially equivalent.

Technology –
The Cuff Pilot™ uses a bellows which moves in relationship to the intra-cuff pressure. As pressures increases the bellows collapses.
Discussion – The use of a bellows which moves in relationship to the intra-cuff pressure is identical to the predicate EasyCuff™ (K102704). The only differences is that for the proposed device the bellows compresses with increasing pressure while the predicate EasyCuff™ bellows expands with increasing pressure. Each device has color coded zones, which represent pressures, which informs the user of the relative cuff pressure within the zone. Any difference does not raise any new safety or effectiveness concerns, thus the proposed device is considered substantially equivalent.

Summary of Non-clinical Testing
The following is a summary of non-clinical bench testing.

Materials –
There are no materials of the Cuff Pilot™ in contact with the patient or in the gas pathway.
Discussion – We have performed ISO 10993-1 cytotoxicity testing on the Cuff Pilot™. The results were non-reactive.

Performance –
We have performed a number of tests to demonstrate the accuracy and repeatability of the measured pressure for the Cuff Pilot™. The performance is similar to the predicate, EasyCuff™ (K102704).

The tests performed are:

- Real-time age testing – 3 years
- Accuracy across the pressure zone / range
- Repeatability
- Subjected samples to aging and exposure to cold and hot temperatures
- Drop / Shipping test

Discussion – The performance specifications of the Cuff Pilot™ and the predicate are substantially equivalent.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.

SureSeal™ with Cuff Pilot™
SureSeal™ is only offered with the Cuff Pilot™ is standard Supraglottic airway similar in design and function to the LMA Classic™. It is considered a Class 1 exempt device but we are seeking to have the Cuff Pilot™ attached as well as seeking MR Safe environment of use.

Attribute	Predicate LMA Classic™ (K130304)	Proposed Device SureSeal™ with Cuff Pilot™
Classification	Procode –CAE – airway, oropharyngeal CFR – 868.5110 Class 1 - exempt	Procode –CAE – airway, oropharyngeal CFR – 868.5110 Class 1 - exempt
Indications for Use	LMA Classic™ is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients and emergency procedures using either spontaneous or Positive Pressure Ventilation (PPV). • An alternative to a face mask. • An airway device in routine anesthesia procedures. • Securing the immediate airway in anticipated or unexpected difficult airway situations. • Use in elective surgical procedures where tracheal intubation is not necessary. • Establishing an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient requiring artificial ventilation when tracheal intubation is not possible.	The SureSeal™ supraglottic airway is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients and emergency procedures using either spontaneous or Positive Pressure Ventilation (PPV). • An alternative to a face mask. • An airway device in routine anesthesia procedures. • Securing the immediate airway in anticipated or unexpected difficult airway situations. • Use in elective surgical procedures where tracheal intubation is not necessary. • Establishing an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient requiring artificial ventilation when tracheal intubation is not possible.
Patient population	Patients who need an artificial airway	Patients who need an artificial airway
Environments of use	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient needs an artificial airway. It may also be used in MR suites as MR Conditional.	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient needs an artificial airway. It may also be used in MRI suites when attached to airways that are MR Safe.
Technology	Inflatable cuff and tube that rest above the glottis opening	Inflatable cuff and tube that rest above the glottis opening
Method of inflating cuff	Use integrated pilot check valve with a separate syringe. Manual	Used with Cuff Pilot™ and a separate syringe. Manual
Available in sizes	Sizes 1 to 6	Sizes 1 to 6
Single patient, disposable	Yes	Yes

Attribute	Predicate LMA Classic™ (K130304)	Proposed Device SureSeal™ with Cuff Pilot™
MRI Use	MR Conditional	MR Safe based upon the lack of materials which contain metal or are magnetic per ASTM F2052-06, rationale
Biocompatibility	Surface and Externally communicating contact (indirect gas pathway) Tissue / Mucosa contact Limited duration	Surface and Externally communicating contact (indirect gas pathway) Tissue / Mucosa contact Limited duration
Shelf-life	3 years	3 years
Performance Testing		Age Hot / Cold temperature Drop / shipping

Substantial Equivalence Discussion:
The SureSeal™ is viewed as substantially equivalent to the predicate device because:

Indications –
The SureSeal™ is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients and emergency procedures using either spontaneous or Positive Pressure Ventilation (PPV).
Discussion – The predicate, LMA Classic™ (K130304) is also designed to achieve and maintain and airway. There are no differences, thus there are no new safety or effectiveness concerns raised, thus the proposed device is considered substantially equivalent.

Environment of Use –
The SureSeal™ has the same environment of use as the predicate including use in MRI suites.
Discussion – The SureSeal™ and the Cuff Pilot™ have no magnetic materials and thus can be considered MR Safe. The predicate is MR Conditional because the inflation check valve does contain magnetic materials. This difference does not raise any new safety or effectiveness concerns that have not been addressed in the rationale and thus the proposed device can be considered substantially equivalent.

Patient Population –
The SureSeal™ has the same patient population as the predicate.
Discussion – There are no differences between the predicate and the proposed device, thus it can be considered substantially equivalent.

Technology –
The SureSeal™ employs the same technology and principle of operation as the predicate.
Discussion – The design and technology is similar between the devices and there are no differences which would raise any new safety or effectiveness concerns, thus the proposed device is considered substantially equivalent.

Materials –
The materials are similar between the devices.
Discussion – We have performed ISO 10993-1 testing for the materials for the SureSeal™. Based upon ISO 10993-1 and G95-1 the SureSeal™ would be considered as:

- Surface Contact and Externally communicating (indirect gas pathway)
- Tissue / Mucosa contact
- Limited duration (<24 hours)

This is identical to the predicate LMA Classic™ (K130304).

Performance –
We have performed a number of tests on the SureSeal™ including age / shelf-life, hot and cold temperatures and drop /shipping testing.
Discussion – The SureSeal™ met it specifications after these tests.

Summary of Non-clinical Testing
The following is a summary of non-clinical bench testing.

Materials –
We have performed ISO 10993-1 testing for the materials of the SureSeal™.

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity

Performance –
We have performed a number of tests which included:

- Real-time age testing – 3 years
- Subjected samples to aging and exposure to cold and hot temperatures
- Drop / Shipping test

Results – The SureSeal™ met its performance specifications.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.