K130304

510(k) Summary
Page 1 of 9
30-May-14

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Teleflex Medical, Inc.
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Official Contact:	Liz Paul Director, Regulatory Affairs/Quality Engineering Anesthesia/Respiratory
Trade Name:	LMA Unique™ LMA Classic™ LMA Classic™ Excel LMA Flexible™ LMA Flexible™ Single Use LMA ProSeal™ LMA Fastrach™ Single Use LMA Supreme™
Common/Usual Name:	Airway, oropharyngeal, anesthesiology
Classification Name:	CAE – airway, oropharyngeal, anesthesiology 21 CFR 868.5110 Class I
Predicate Devices:	LMA Classic™ - K904834 LMA Supreme™ - K001425 All others are Class 1 exempt
Trade Name:	LMA Fastrach™ ETT LMA Fastrach™ ETT Single Use
Common/Usual Name:	Tracheal tube
Classification Name:	BTR – tracheal tube 21 CFR 868.5730 Class 2
Predicate Devices:	LMA Fastrach™ ETT (reusable) – K991580 LMA Fastrach™ ETT Single Use – K051993

Modification and Changes to Predicate:
To seek MR Conditional environment of use. There have been no other modifications to any of the LMA product series.

Device Description:
The LMA™ family of airways includes 2 types of airways:

- Generically referred to as supraglottic airways and

- Tracheal Tubes specific for use with the LMA Fastrach™ device

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The LMA™ family of airways includes 2 types of airways:

- Generically referred to as supraglottic airways and
- Tracheal Tubes specific for use with the LMA Fastrach™ device

The supraglottic airways are airways that incorporate a large cuff that sits above the glottic opening and the opposite end has a standard 15 mm OD connector that connector to a gas source.

Figure 1 is a typical example of the LMA Classic™. The LMA Unique™, Classic™ Excel are also similar in design, the differences are listed.

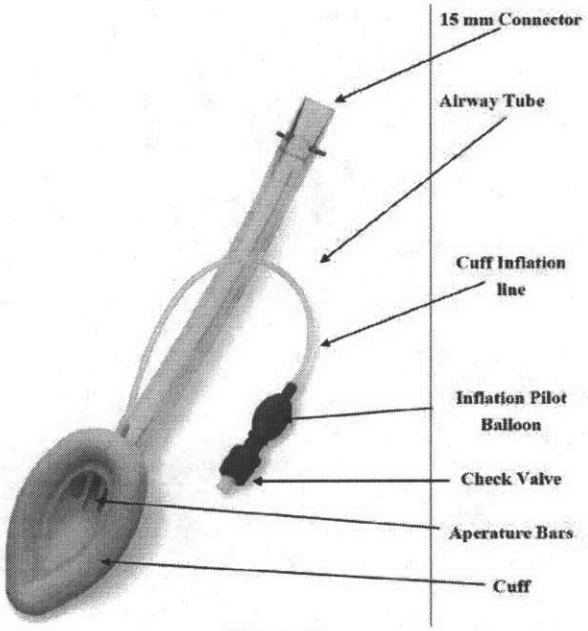


Figure 1

The LMA Flexible™ is the same as the Classic™ except that the shaft is wire reinforced allowing for great flexibility.

Figure 2 is a picture of the LMA ProSeal™ which has a second lumen for drainage.

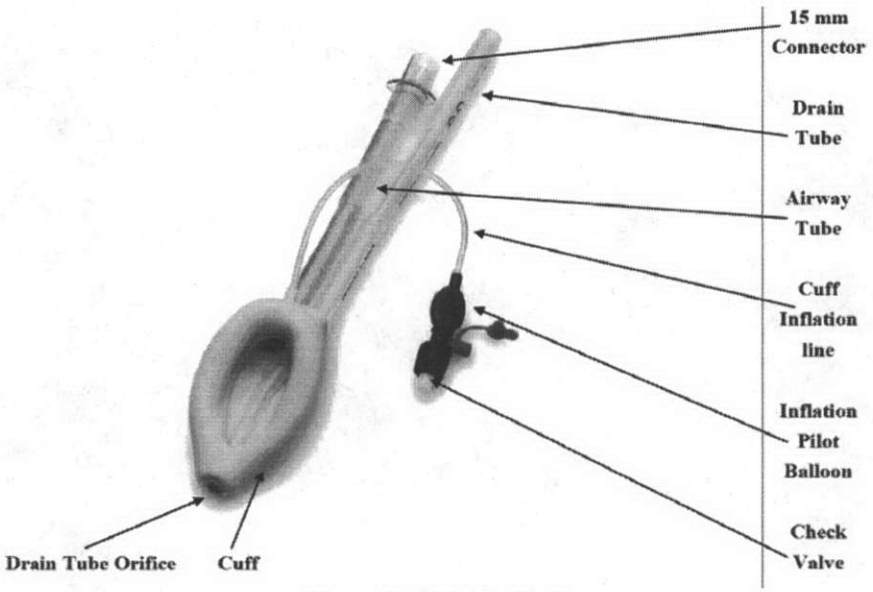


Figure 2 LMA ProSeal

Figure 3 is the LMA Fastrach™ single use which has a rigid handle to assist with insertion.

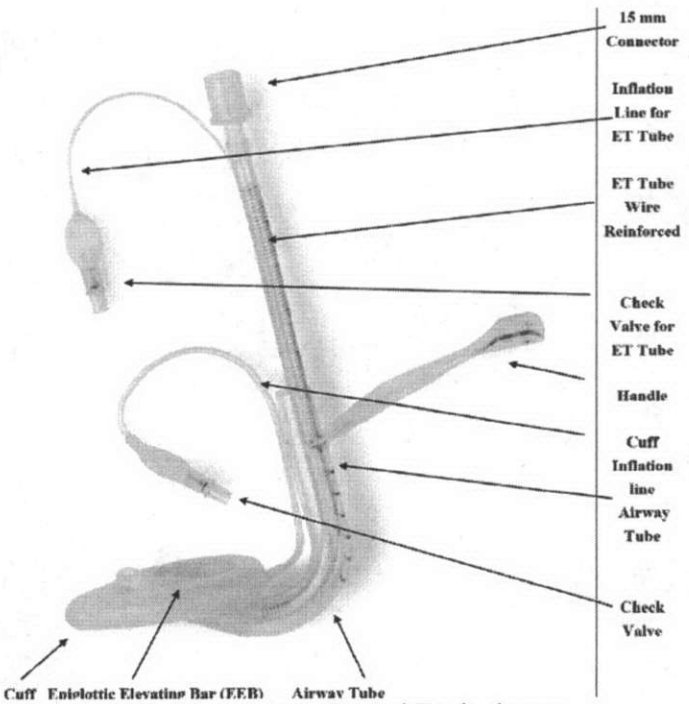


Figure 3 – LMA Fastrach™ single use

Table 1 below lists the styles and their general design.

These have been and continued to be considered Class 1 exempt medical devices, however to be marketed for use in MRI suites, even as Class 1 devices requires testing and a review by CDRH for the change in indications for use as MR conditional.

The LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use is straight, cuffed, wire reinforced tracheal tube that is designed to be used with the LMA Fastrach™ supraglottic airway.

Table 1 – Overall Device Description

Product	Brief Description
Classification CAE – oropharyngeal airway	
LMA Classic™	Standard cuff – reusable
LMA Unique™	Same as Classic™ except single use
LMA Classic Excel™	Similar to Classic™ but can be reused more times
LMA Flexible™	Similar to Classic™ except with flexible wire reinforced shaft Reusable and Single Use models
LMA ProSeal™	Similar to Classic™ but with built-in drain lumen
LMA Fastrach™	To help facilitate intubation, has a rigid shaft to help with insertion / placement
LMA Supreme™	Similar to LMA ProSeal™ with built-in drain lumen and is single use
Classification – BTR – tracheal tube	
LMA Fastrach™ ETT	Endotracheal tube which is wire reinforced to be used only with the LMA Fastrach™

Indications for Use:

Classification - CAE
The LMA Fastrach™ is indicated for use as a guide for intubation of the trachea The LMA Fastrach™ is indicated for achieving and maintaining control of the airway during routine and emergency situations, including anticipated or unexpected difficult airways. The LMA

Fastrach™ is indicated as a method of establishing an airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

LMA Classic™, Classic™ Excel, Unique™ and Flexible™ are 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 LMA Supreme™ is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients using either spontaneous or Positive Pressure Ventilation (PPV). LMA Supreme™ is also intended for use as a rescue device in emergency situations.

- An alternative to a face mask.
- An airway device in routine anesthesia procedures.
- A rescue airway device in anticipated or unexpected difficult airway situations.
- A rescue airway device in CPR procedures. The LMA Supreme™ may be used to establish an immediate clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation.
- It may also be used to secure an immediate airway when tracheal intubation is precluded by lack of available expertise or equipment, or when attempts at tracheal intubation have failed.

The LMA ProSeal™ is indicated for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients using either spontaneous or Positive Pressure Ventilation (PPV). LMA ProSeal™ is also intended for use as a rescue device in emergency situations.

- The LMA ProSeal™ is indicated for use as:
- An alternative to a face mask.
- An airway device in routine anesthesia procedures.
- A rescue airway device in anticipated or unexpected difficult airway situations.
- A rescue airway device in CPR procedures.
- The LMA ProSeal™ may be used to establish an immediate clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation.

Classification - BTR

The LMA Fastrach™ ETT is indicated for tracheal intubation through the LMA Fastrach™ or for conventional intubation of the trachea using direct or indirect laryngoscopy.

Environment of Use:
Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

Predicate Device Comparison:

Table 2 – Comparison to Predicates - CAE Classification

Characteristic	LMA™ Airway devices	Predicate LMA™ Airway devices (Class 1 exempt) LMA Classic™ - K904834 LMA ProSeal™ - K001425
Product Classification	CAE - airway, oropharyngeal, anesthesiology CFR 868.5110, Class 1	CAE - airway, oropharyngeal, anesthesiology CFR 868.5110, Class 1
Intended Use	Devices inserted into a patient's pharynx through the mouth to provide a patent airway (see above detailed description) Adding can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.	The LMA family of airway have the substantially equivalent indications for use: Devices inserted into a patient's pharynx through the mouth to provide a patent airway.
Environment of Use	MR environments Not to exceed 3.0 Tesla	Not tested
Performance Testing	ASTM F2052-06e1 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Effects of MR conditions on the check valve	

Substantial Equivalence Comparison to Predicates:

Discussion of Classification – CAE

The LMA Unique™, LMA Classic™, LMA Classic™ Excel LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™ are substantially equivalent to the predicate device because:

Indications –

- Substantially equivalent to predicate – LMA Unique™, LMA Classic™, LMA Classic™ Excel LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™
- Intended to provide a patent airway in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Discussion: There are no differences between the devices only the addition of the MR conditional indication.

Technology –

- Substantially equivalent to predicate – LMA Unique™, LMA Classic™, LMA Classic™ Excel, LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™

Discussion: There are no differences in technology between the devices. Both devices are Class 1 exempt

Materials –

- There have been no changes in materials

Discussion: There are no differences in materials between the devices and they are Class I exempt devices.

Environment of Use –

- Addition of the MR Conditional environment

Discussion: The addition of the Magnetic Resonance (MR) environments up to 3.0 Tesla strength has been tested per ASTM F2502-06e1.

Table 3 - Comparison to Predicates – BTR Classification

Characteristic	LMA Fastrach™ ETT And LMA Fastrach™ ETT Single Use	Predicate LMA Fastrach™ ET Tube K991580 K051993
Product Classification	BTR – tracheal tube CFR 868.5730 Class 2	BTR – tracheal tube CFR 868.5730 Class 2
Indications for Use	The LMA Fastrach™ ETT is indicated for tracheal intubation through the LMA Fastrach™ or for conventional intubation of the trachea using direct or indirect laryngoscopy. Adding can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.	The LMA Fastrach™ ETT and LMA Fastrach™ Single Use is indicated for airway management by oral intubation of the trachea. Reinforced ETT may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation.
Environment of Use	MR environments Not to exceed 3.0 Tesla	Not tested
Performance Testing	ASTM F2052-06e1 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Effects of MR conditions on the check valve	

Substantial Equivalence Comparison to Predicates:

Discussion of Classification – BTR

The LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use are substantially equivalent to the predicate device because:

Indications –

- Substantially equivalent to predicate – LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use
- Intended to provide a patent airway in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Discussion: There are no differences between the devices only the addition of the MR conditional indication. Predicate LMA Fastrach™ ETT (reusable) – K991580 and LMA Fastrach™ ETT Single Use – K051993.

Technology –

- Substantially equivalent to predicate LMA Fastrach™ ETT (reusable) – K991580 and LMA Fastrach™ ETT Single Use – K051993.

Discussion: There are no differences in technology between the devices.

Materials –

- There have been no changes in materials

Discussion: There are no differences in materials between the predicate LMA Fastrach™ ETT (reusable) – K991580 and LMA Fastrach™ ETT Single Use – K051993.

Environment of Use –

- Addition of the MR Conditional environment

Discussion: The addition of the Magnetic Resonance (MR) environments up to 3.0 Tesla strength has been tested per ASTM F2502-06e1.

Non-clinical Comparative Performance and Specifications:

MRI Testing

Bench testing per ASTM F2502-06e1 demonstrated that the devices meet the pass / fail criteria and thus there are no new risks associated with MR Conditional use. We have performed testing in accordance to ASTM F2052-06e1.

We have performed testing in accordance to ASTM F2052-06e1 on 4 models of the LMA™ devices.

- LMA ProSeal™
- LMA Fastrach™ ETT
- LMA Supreme™
- LMA Flexible™

- As noted above the LMA Classic™, LMA Unique™, LMA Classic Excel™, and LMA Fastrach™ Single Use are almost substantially equivalent to the LMA Supreme™ as they are of complete plastic, non-magnetic materials, except for the Check Valve, which is substantially equivalent for each style as was part of the MRI evaluation of the LMA Supreme™.

  Since the LMA Supreme™ meets the ASTM F2502-06e1 requirements, one can justify that the LMA Classic™, LMA Unique™, LMA Classic Excel™, and LMA Fastrach™ Single Use would also meet the requirements.

For those devices which exhibited a deflection greater than 45 degrees during their intended use, they will be held in place or "fixed in place" with adhesive tape, cloth material, and/or a plastic holding device. Based upon this normal condition of use, it was deemed that the device will not dislodge or move is properly fixed in place. Our instructions include that fixation in a MRI environment is mandated.

Effects of MR conditions on check valve

We evaluated the performance of the inflation check valve used in each device during MRI exposure and post exposure to determine if there was an influence. There was no affects.

Substantial Equivalence Conclusion:

The addition of MR Conditional environment of use to the LMA airway devices does not raise any new safety or performance questions which have not been addressed via testing to ASTM F2502-06e1.

The bench testing per ASTM F2502-06e1 and the requirement of fixing the device in place which is the normal practice support that the devices are substantially equivalent to the predicates.

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 30, 2014

Teleflex Medical, Inc.
c/o Paul Dryden
Regulatory Consultant
2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

Re: K130304
Trade/Device Name: LMA Unique, LMA Classic, LMA Classic Excel, LMA Flexible, LMA Flexible Single Use, LMA ProSeal, LMA Fastrach Single Use, LMA Fastrach ETT, LMA Fastrach ETT Single Use, LMA Supreme
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR, CAE
Dated: May 23, 2014
Received: May 27, 2014

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.

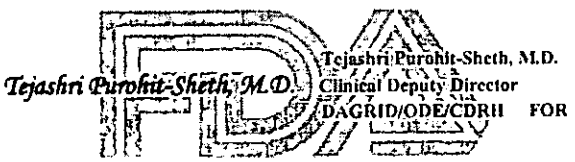
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Indications for Use Statement

510(k) Number: K130304 (To be assigned)

Device Name:

LMA Unique™
LMA Classic™
LMA Classic Excel™
LMA Flexible™
LMA Flexible™ Single Use
LMA ProSeal™
LMA Fastrach™ Single Use
LMA Supreme™

Indications for Use:

The LMA Unique™, LMA Classic™, LMA Classic Excel™, LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™ are devices inserted into a patient's pharynx through the mouth to provide a patent airway. These can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney -S
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Indications for Use Statement

510(k) Number: K130304 (To be assigned)

Device Name: LMA Fastrach™ ETT
LMA Fastrach™ Single Use

Indications for Use:

The LMA Fastrach™ ETT (reusable) and LMA Fastrach™ ETT Single Use are indicated for airway management by oral intubation of the trachea. Reinforced ETT may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation.

These can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

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)

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