



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K130304

Date Received by DCC: February 7, 2013

Lead Reviewer: Mario Mendoza

Branch: ANDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed

Yes

No

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

×

Comments?

2. Is the application with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."

×

Comments?

3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question is no, mark "No." If there was no RFD, skip this question.

Comments? N/A

4) Is this device type eligible for a 510(k) submission?

If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."

×

Comments?

5) Is there a pending PMA for the same device with the same indications for use? Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024 If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
 If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
 If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
 If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
 If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?	(b)(4)	

Elements of a Complete Submission (RTA Items)

Revised process under FOIA Request 2021-0001 Released by CDRH on 4/10/24

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	×			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	×			
a) Device trade name or proprietary name	×			
b) Device common name	×			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	×			
4) Submission contains 510(k) Summary or 510(k) Statement	×			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	×			
b) Statement contains all elements per 21 CFR 807.93			×	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format.	×			×
Comments?				
6) Submission contains Class III Summary and Certification. See recommended content.	×			
7) Submission contains clinical data			×	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	×			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	×			×
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.		×		

Comments?

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

B. Device Description

10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	×			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×			
c) A list and description of each device for which clearance is requested.	×			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	×			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	×			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	×			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	×			

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	×			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	×			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	×			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	×			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

Elements of a Complete Submission (RTA Items)

Redacted Processed Under FOIA Request 2022-0001 Released by CDRH on 4/10/2024

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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b) Technology, including features, materials, and principles of operation

×

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))

×

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.

×

×

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).

b) Submission includes directions for use that

- include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND
- includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D

×

Comments?

(b)(4)

18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also [Alternative to Certain Prescription Device Labeling Requirements](#)]

×

×

Comments?

(b)(4)

19) General labeling provisions

×

a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).

×

b) Labeling includes device common or usual name. (21 CFR 801.61)

×

Comments?

(b)(4)

20)

a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.

×

Elements of a Complete Submission (RTA Items)
Revised Process and Order for RTA Request (21 CFR 807.87) Released by FDA on 11/19/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
--	-----	----	-----	---------

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.

F. Shelf Life

26) Proposed shelf life/expiration date stated

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

Comments?

(b)(4)

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

H. Software

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

✗

does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

I. EMC and Electrical Safety

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Elements of a Complete Submission (RTA Items)
Revised Process and Form Request 2022-2023 Released by CDHRH on 4/14/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

☒ does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

☒

37)

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.

☒

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

☒

c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

☒

38) If literature is referenced in the submission, submission includes:

☒

39) For each completed nonclinical (i.e., animal) study conducted

☒

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

☒

Submission states that the device: (one of the below must be checked)

is an in vitro diagnostic device.

☒ is not an in vitro diagnostic device.

Comments?

Decision: ☐ Accept ☒ **Refuse to Accept**

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Mario Mendoza -S 2013.02.22 16:14:38 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Lester W. Schultheis Jr 2013.02.22 16:17:42 -05'00'
Division Sign-Off (digital signature optional)*	Kwame O. Ulmer 2013.02.22 16:42:58 -05'00'

* Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S003

Date: February 11, 2014
To: The Record
From: Mario Mendoza, MD

Office: ODE
Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

(b)(5)

(b)(5)

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SIGNATURES

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mario Mendoza -S 2014.02.11 17:01:04 -05'00'
Branch Chief Sign-Off (Optional)	
Division Sign-Off (Optional)	

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510(k) Summary

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MAY 30 2014

Teleflex Medical, Inc.

2917 Weck Drive

P.O. Box 12600

Research Triangle Park, NC 27709

Tel – 919-433-8076

Fax – 919-433-4996

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 I 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

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

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

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.

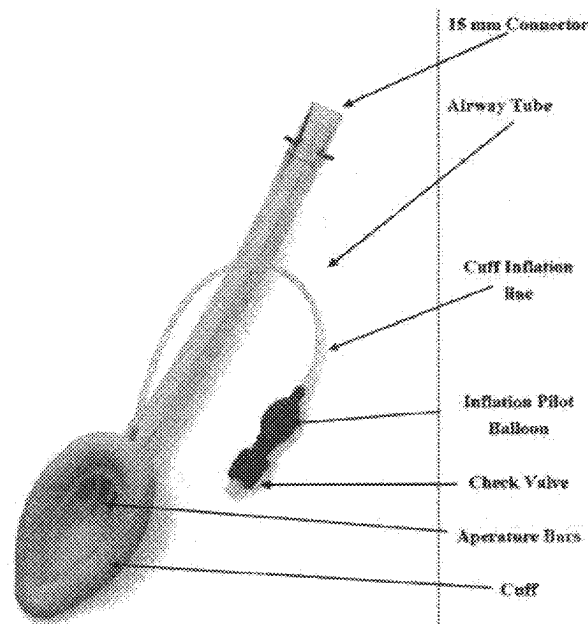


Figure 1

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.

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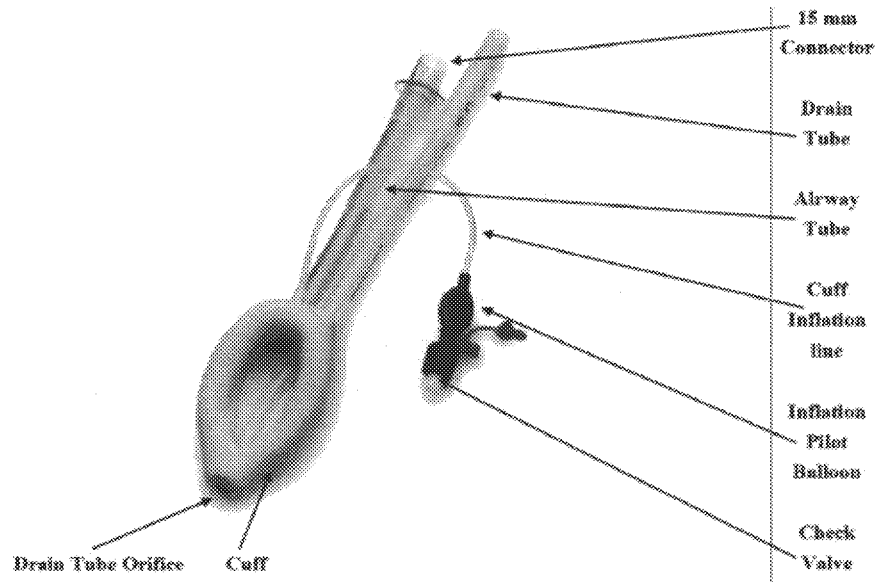


Figure 2 LMA ProSeal

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

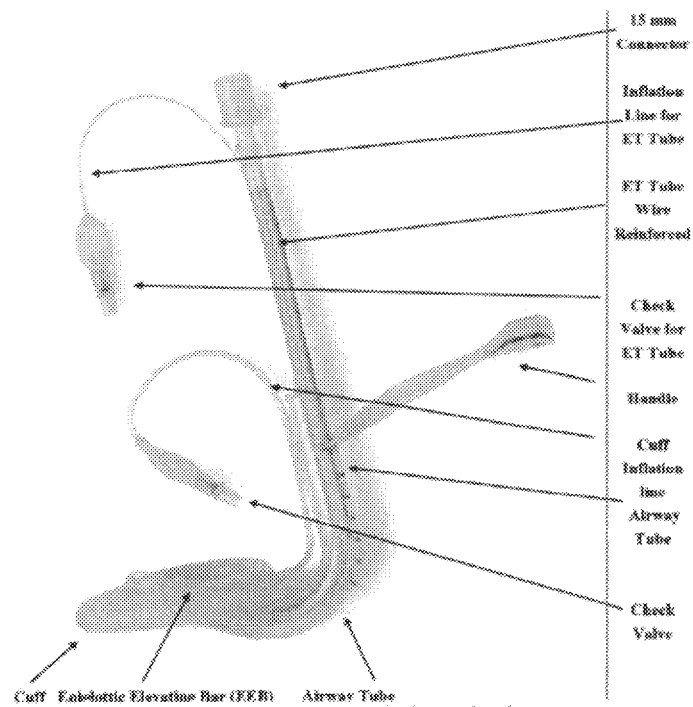


Figure 3 – LMA Fastrach™ single use

Table 1 below lists the styles and their general design.

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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.

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- 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.

510(k) Summary

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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.

510(k) Summary

Page 7 of 9

30-May-14

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 I 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	

510(k) Summary

Page 8 of 9

30-May-14

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™

510(k) Summary

Page 9 of 9

30-May-14

- 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.

Page 2 – Mr. Dryden

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" (21 CFR 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,

 Tejasht Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin L. 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

Page 1 of 1

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney-S
2014.05.29 20:59:02 -04'00'

Page 06.2

PDF PAGE 40 of 263

Indications for Use Statement

Page 1 of 1

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)

Todd D. Courtney-S
2014 05 29 20 59:24
-04'00

A circular stamp from the Food and Drug Administration (FDA) is overlaid on the signature. The text "FDA" is prominently displayed in the center, with "DEPARTMENT OF HEALTH & HUMAN SERVICES" around the perimeter. The date and time "2014 05 29 20 59:24" and the time zone "-04'00" are also visible.

Page 06.3

PDF PAGE 41 of 263



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S004

Date: May 30, 2014

To: The Record

From: Mario Mendoza, MD

Office: ODE

Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

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SIGNATURES

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mario Mendoza -S 2014.05.30 15:12:30 -04'00'
Branch Chief Sign-Off (Optional)	
Division Sign-Off (Optional)	

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market The Laryngeal Mask Company LMA family of airways (K130304). We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. The requested information should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact me via email or at (240) 402-5121. If you need information or assistance concerning the IDE regulations, 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>.

Sincerely yours,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



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.

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Page 2 – Mr. Dryden

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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" (21 CFR 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,


Tejashri Purohit-Sheth, M.D. Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

Thank you for the meeting minutes Mr. Dryden,

Some minor edits included and file attached.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S004

Date: May 30, 2014

To: The Record

From: Mario Mendoza, MD

Office: ODE

Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

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Mario R. Mendoza, M.D., MS

Medical Officer

CDRH/ODE/DAGRID/ANDB

WO66, Room 2563

Office: (240) 402-5121

Mario.Mendoza@fda.hhs.gov

From: Mendoza, Mario

Sent: Wednesday, June 04, 2014 10:13 AM

To: 'Paul Dryden'; Courtney, Todd D

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: RE: K130304 (b)(4)

Mr. Dryden,

We are in discussion with 510k staff and will respond to you shortly.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Tuesday, June 03, 2014 5:48 PM

To: Courtney, Todd D

Cc: Mendoza, Mario; Paul, Liz (liz.paul@teleflex.com<mailto:liz.paul@teleflex.com>); Lovelace, Justin (Justin.Lovelace@teleflex.com<mailto:Justin.Lovelace@teleflex.com>)

Subject: K130304 (b)(4)

Mr. Courtney and Dr. Mendoza:

We received the SE letter today for K130304 - Teleflex LMA airways for MR conditional use, for which we thank you. (b)(4)

(b)(4)

Should you have any questions, please feel free to call me.

I left a voicemail this evening for Todd alerting him of the issue.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

Web - www.promedic.cc<http://www.promedic.cc/>

Twitter - https://twitter.com/ProMedicInc

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<u>12.3</u>	<u>Accessories</u>	<u>6</u>
<u>12.4</u>	<u>Indications for Use</u>	<u>6</u>
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12.1 Background and Differences

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

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

LMA as a company is the world leader in supplying these types of airways.

The supraglottic airways 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 tracheal tube, LMA Fastrach™ ETT, is considered a Class 2 device, for which we are seeking the same change in indications for use as MR conditional.

FDA guidance allows for device reviews to be bundled, even if they are different indications for use and classes, if the review can be performed by the same reviewer.

This case can be supported for this submission as the MR conditional testing is identical for all the LMA™ airway family of products and labeling modifications are identical.

We have prepared separate Indications for Use statements for each product code see **Section 06 – Indications for Use.**

Modifications:

- There have been NO modifications to any of the LMA product series
- We are only seeking MR Conditional labeling

Models under review:

As Class 1 – CFR 868.5110 – C AE – airway, oropharyngeal, anesthesiology

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

As Class 2 – CFR 868.5730 – BTR – tracheal tube

- LMA Fastrach™ ETT (reusable and single use)

12.2 Device Description

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

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

The LMA™ family of supraglottic airways are all very similar in design. The following is a brief description of each style.

The tracheal tube, LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use, are tracheal tubes which are different than the supraglottic airway and were cleared under K991580 and K051993.

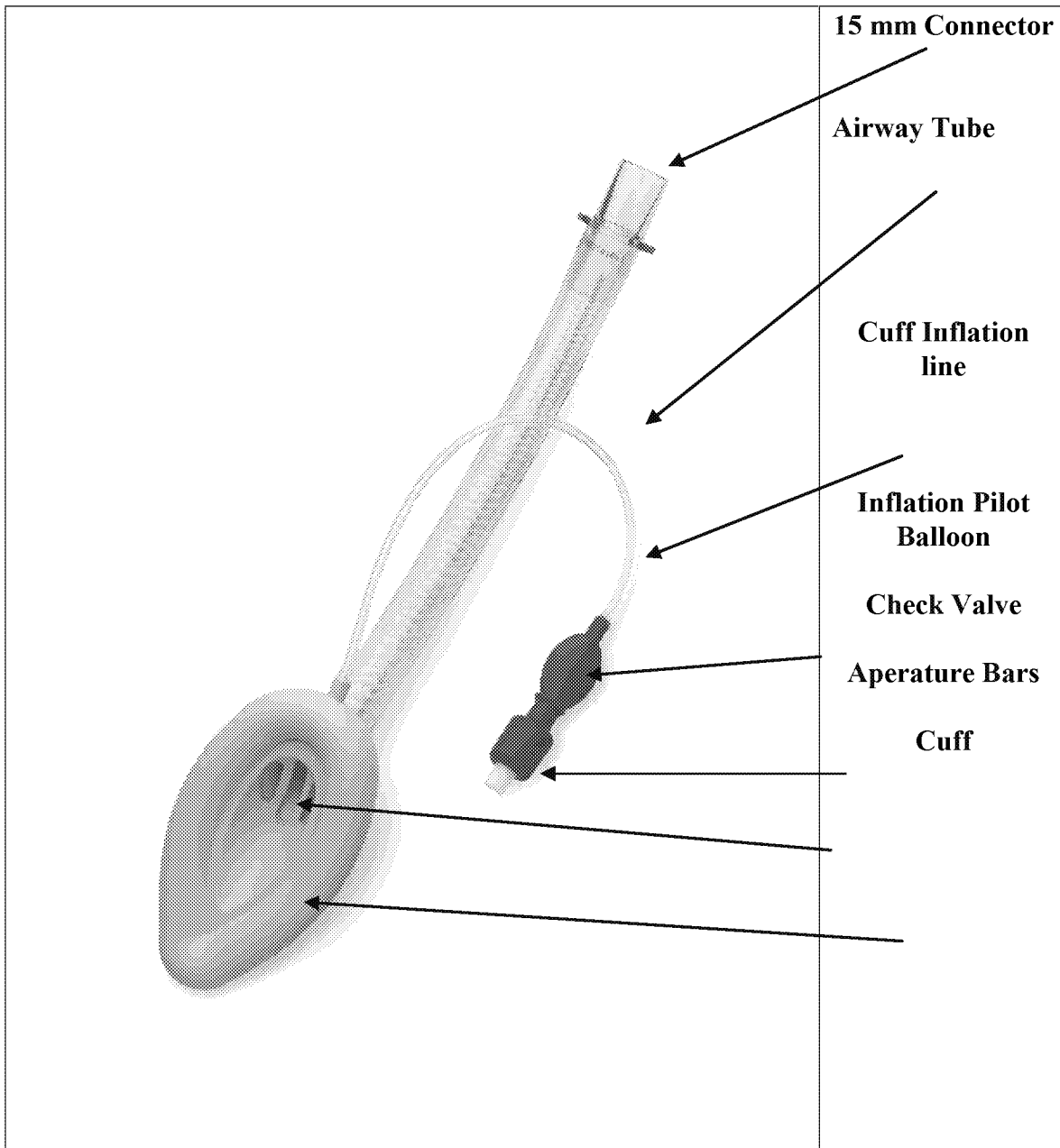
Note that the subject of this submission is to seek clearance for labeling these devices as MR Conditional.

Table 12.1 briefly outlines the different LMA™ products, while **Figures 12.1** represent a typical style.

Table 12.1 – LMA™ Product Description

Product	Brief Description
Classification CAE – oropharyngeal airway	
LMA Classic™	Standard airway – 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™ Single Use	To help facilitate intubation, has a plastic rigid shaft
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™. Available in reusable and single use models.

Figure 12.1 - LMA Classic™



12.3 Accessories and Kit Certification

This submission is limited to seeking MR Conditional indications.

There are no new or additional accessories for the LMA™ airway devices.

12.4 **Indications for Use**

(b)(4)

12.5 **Environments of Use**

Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

12.6 **Materials**

There have been NO changes in materials for any of the devices.

12.7 **Non-clinical Comparative Performance and Specifications**

Bench testing per ASTM D2502-06e1 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. The performance testing for MR conditions is presented in **Section 20 – Performance Testing - Bench.**

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

(b)(4)

12.8 Substantial Equivalence Comparison to Predicates

This submission is seeking the addition of MR conditional environment of use for all of our LMA airway devices.

There have been no changes made to the devices we have only performed testing to demonstrate MR conditional compatibility.

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 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 tracheal tube, LMA Fastrach™ ETT tube, is considered a Class 2 device, for which we are seeking the same change in indications for use as MR conditional.

Table 12.2 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
(b)(4)		
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 Pass criteria is deflection of < 45 degrees	

There are no differences between the proposed device and the predicate except we have performed testing to determine MR Conditional performance per ASTM F2502-06e1.

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 –

- Identical 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 –

- Identical 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 demonstrated to be safe per ASTM F2502-06e1 testing.

Performance Testing

- Complies with ASTM F2502-06e1

Discussion: Testing has been performed according to ASTM F2052-06e1 for deflection in a 3.0 Tesla environment and passed.

Discussion of Classification – BTR

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

Indications –

(b)(4)

Technology –

- Identical 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 demonstrated to be safe per ASTM F2502-06e1 testing.

Performance Testing

- Complies with ASTM F2502-06e1

Discussion: Testing has been performed according to ASTM F2052-06e1 for deflection in a 3.0 Tesla environment and passed.

Substantial Equivalence Conclusion:

The addition of MR Conditional environment of use to the LMA airway devices do not raise any new safety or performance questions which have not been address via testing to ASTM F2502-02.

Bench testing per ASTM D2502-02 demonstrated that the devices meet the pass / fail criteria. Thus they can be found substantially equivalent.



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CONSULTING MEMO

Date: February 10, 2014

To: Mario Mendoza, M.D., M.S.
CDRH/ODE/DAGRID/ANDB

From: Daniel Krainak, PhD
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

Subject: K130304/S003
Laryngeal Mask Airways (LMAs)
Laryngeal Mask Company

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IX. Signature

A handwritten signature in black ink, appearing to read 'DK', is written over a large, light gray, semi-transparent 'FDA' watermark.

Daniel Krainak

2014.02.10 15:12:46 -05'00'



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S003

Date: February 11, 2014
To: The Record
From: Mario Mendoza, MD

Office: ODE
Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

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<u>13</u>	<u>Device Description</u>	<u>Page</u>
<u>13.1</u>	<u>Background and Differences</u>	<u>2</u>
<u>13.2</u>	<u>Device Description</u>	<u>3</u>
<u>13.3</u>	<u>Accessories and Kit Certification</u>	<u>13</u>
<u>13.4</u>	<u>Indications for Use</u>	<u>13</u>
<u>13.5</u>	<u>Contraindications</u>	<u>14</u>
<u>13.6</u>	<u>Environments of Use</u>	<u>14</u>
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<u>13.8</u>	<u>Software</u>	<u>15</u>
<u>13.9</u>	<u>Non-clinical Performance Testing</u>	<u>15</u>
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13.1 Background and Differences

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

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

LMA as a company is the world leader in supplying these types of airways.

The supraglottic airways 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 tracheal tube, LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use, are considered a Class 2 devices, for which we are seeking the same change in indications for use as MR conditional.

FDA guidance allows for device reviews to be bundled, even if they are different indications for use and classes, if the review can be performed by the same reviewer.

This case can be supported for this submission as the MR conditional testing is identical for all the LMA™ airway family of products and labeling modifications are identical.

We have prepared separate Indications for Use statements for each product code see **Section 06 – Indications for Use**.

Modifications:

- There have been NO modifications to any of the LMA product series
- We are only seeking MR Conditional labeling

Models under review:

As Class 1 – CFR 868.5110 – C AE – airway, oropharyngeal, anesthesiology

- LMA Unique™
- LMA Classic™
- LMA Classic Excel™
- LMA Flexible™ (reusable)
- LMA Flexible™ Single Use
- LMA ProSeal™
- LMA Fastrach™ Single Use
- LMA Supreme™

As Class 2 – CFR 868.5730 – BTR – tracheal tube

- LMA Fastrach™ ETT (reusable)
- LMA Fastrach™ ETT Single Use

13.2 Device Description

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

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

The LMA™ family of supraglottic airways are all very similar in design. The following is a brief description of each style.

The tracheal tube, LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use, are tracheal tubes which are different than supraglottic airways and were cleared under K991580 and K051993.

Note that the subject of this submission is to seek clearance for labeling these devices as MR Conditional.

Table 13.1 briefly outlines the different LMA™ products, while **Figures 13.1 to 13.9** are representative pictures of each style.

Table 13.1 – LMA™ Product Description

Product	Brief Description
Classification CAE – oropharyngeal airway	
LMA Classic™	Standard airway – 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 metal rigid shaft
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™

The following are pictures of each. One will notice that they are all very similar in design.

Figure 13.1 - LMA Classic™

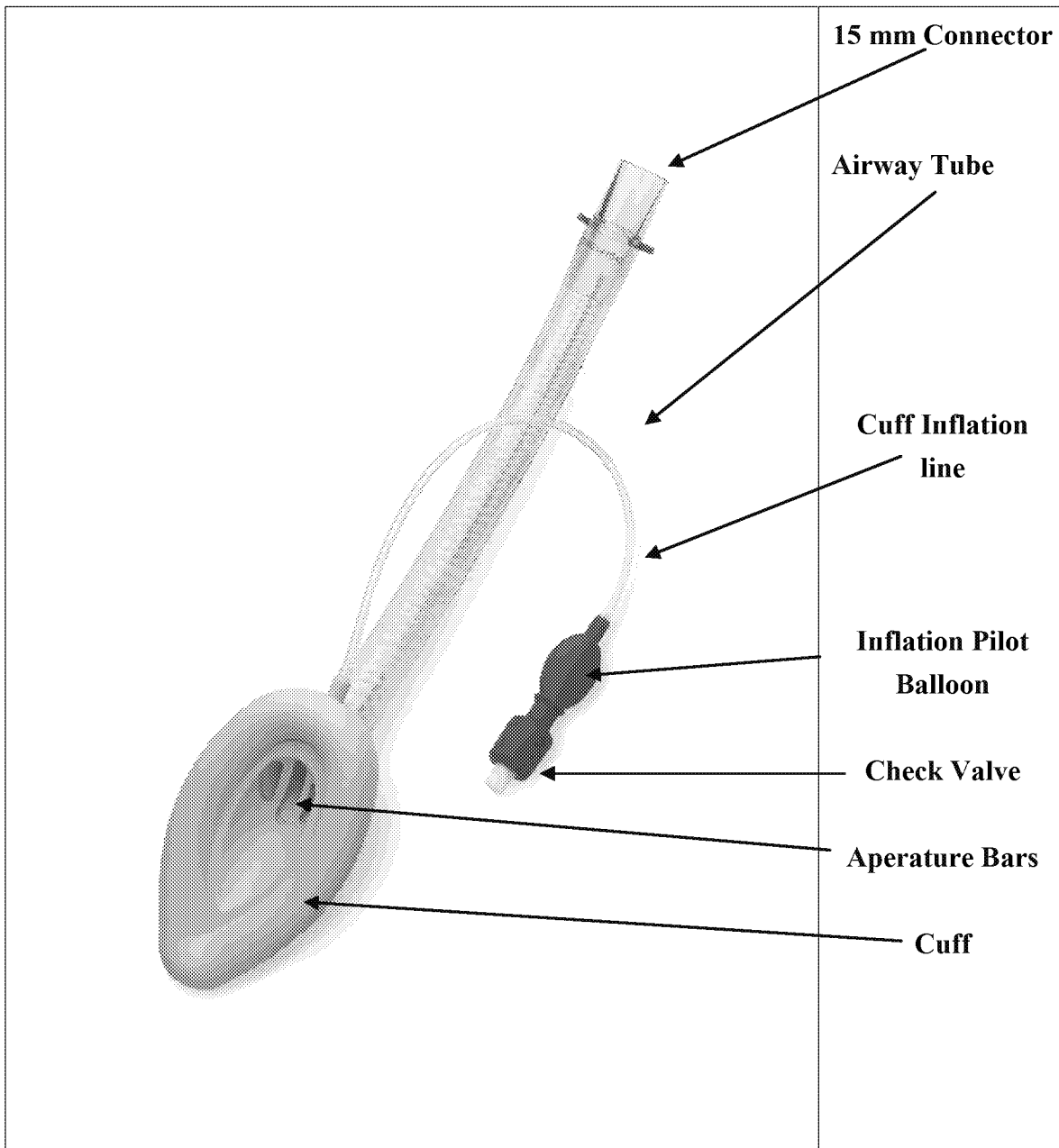


Figure 13.2 - LMA Unique™

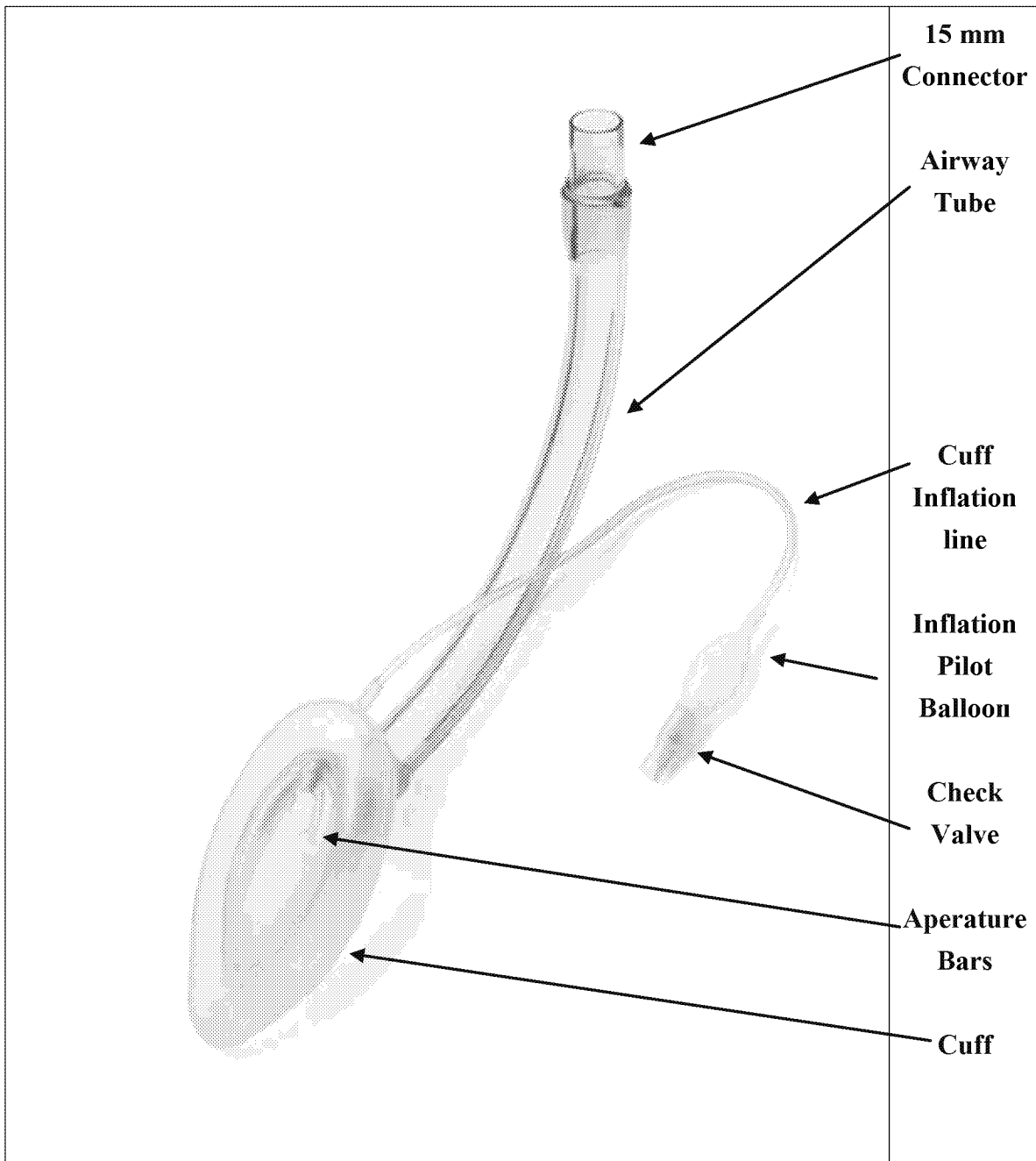


Figure 13.3 – LMA Classic Excel™

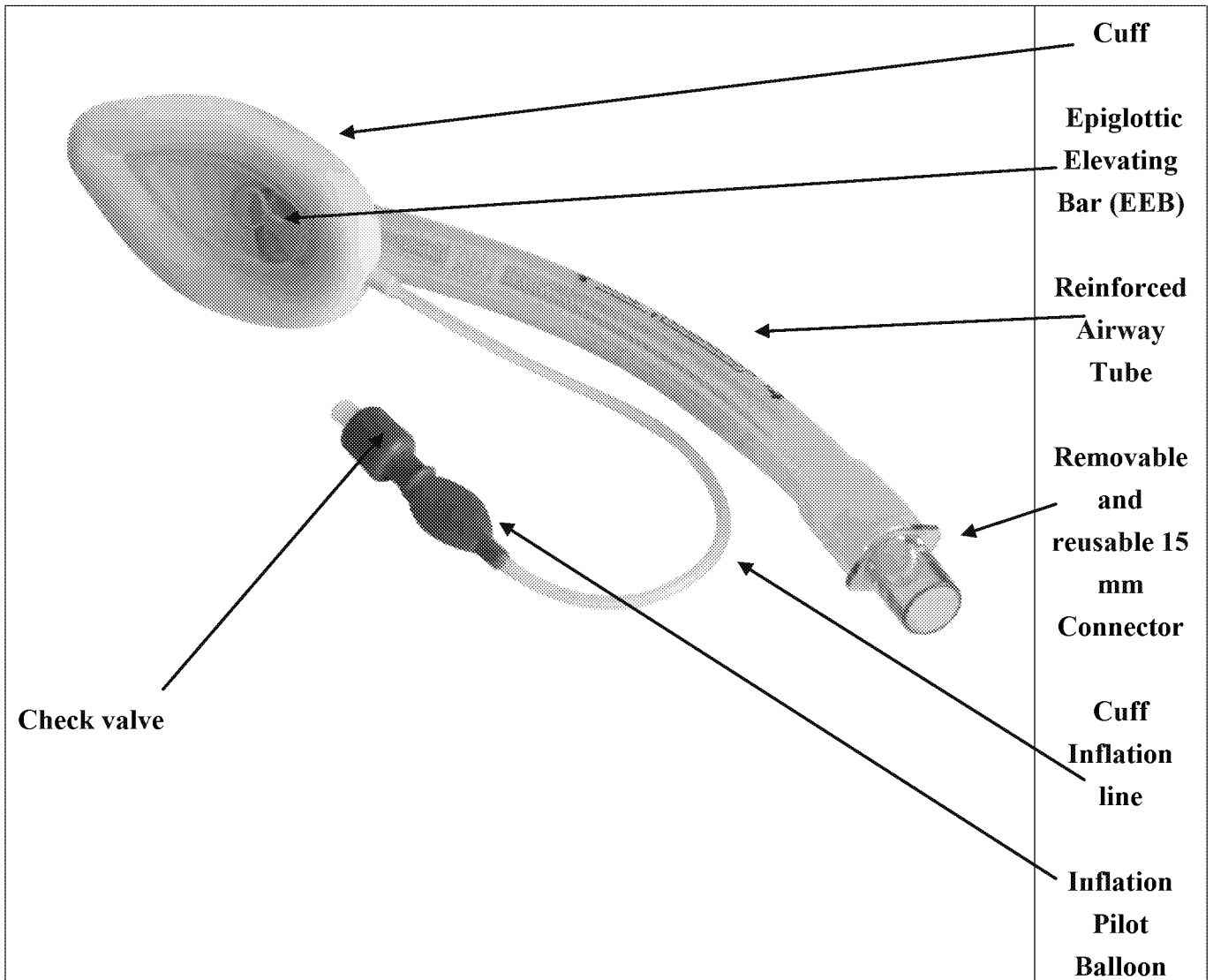


Figure 13.4 - LMA Flexible™ (reusable and single use)

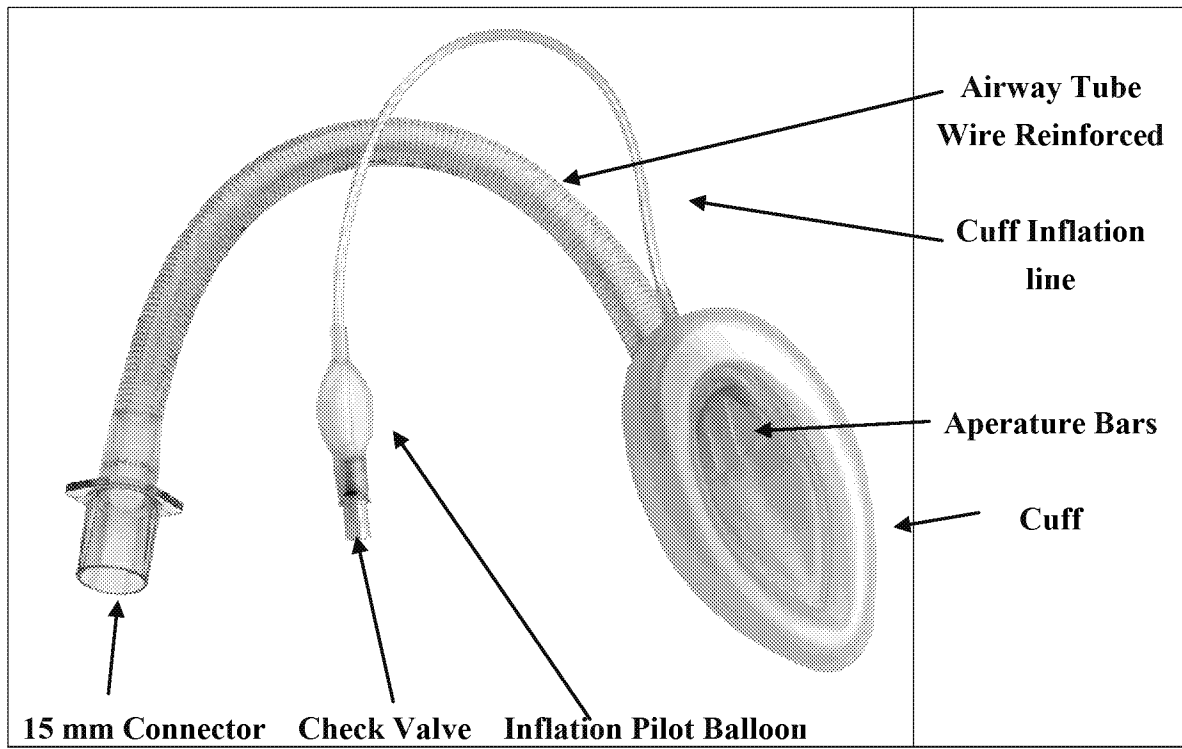


Figure 13.5 - LMA ProSeal™

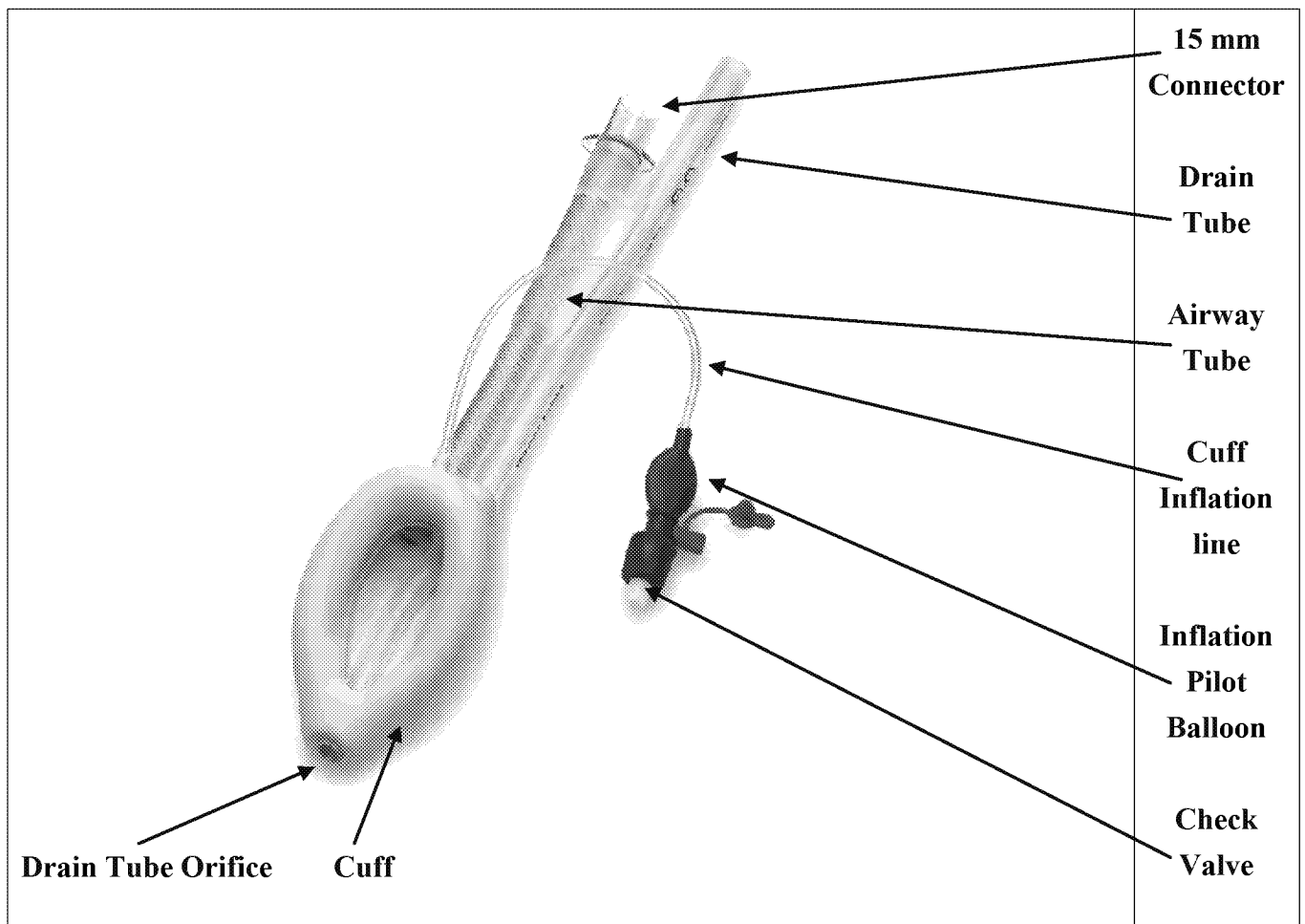


Figure 13.6 - LMA Fastrach™ (single use)

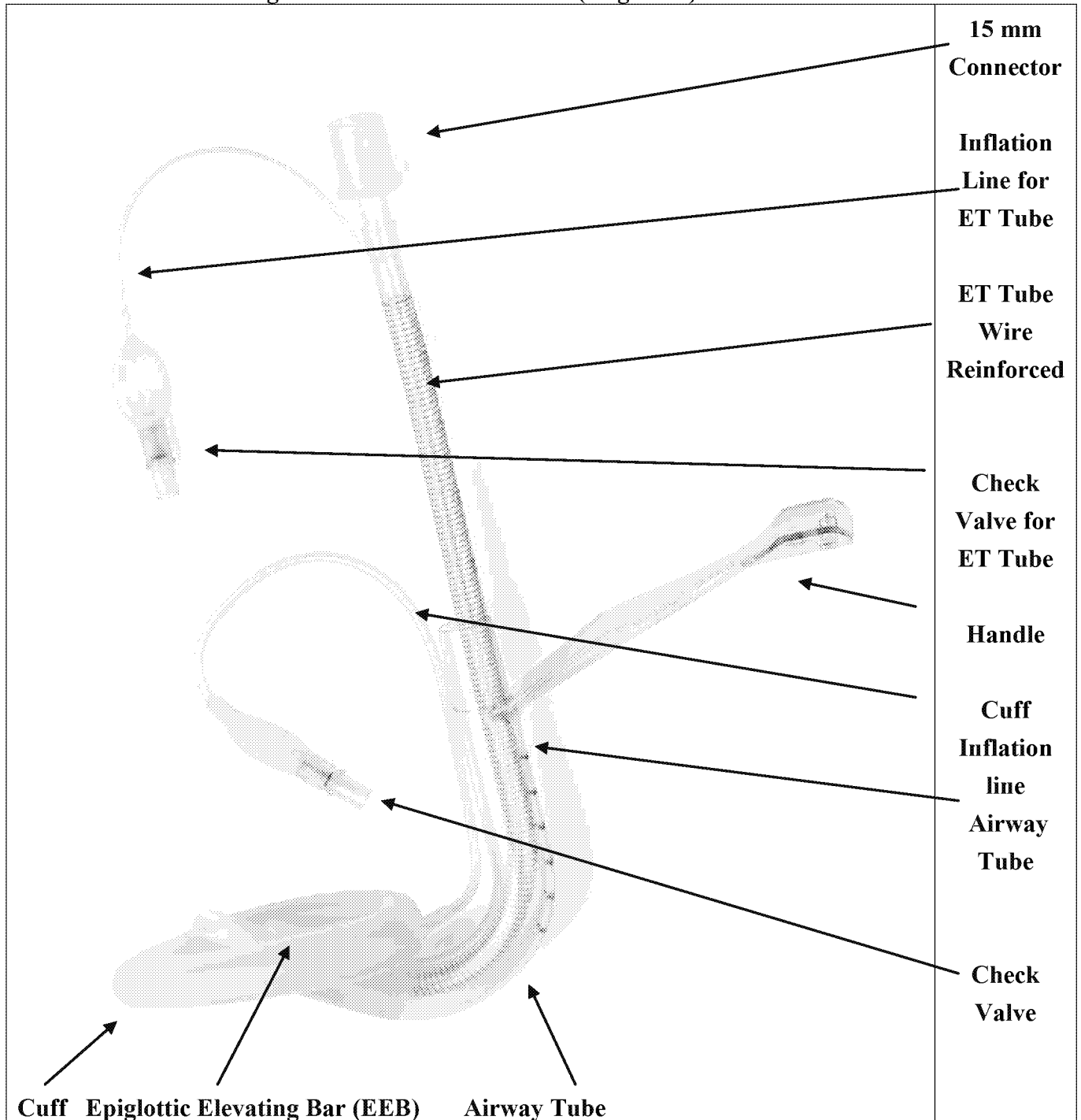


Figure 13.7 - LMA Fastrach™ (Reusable use)

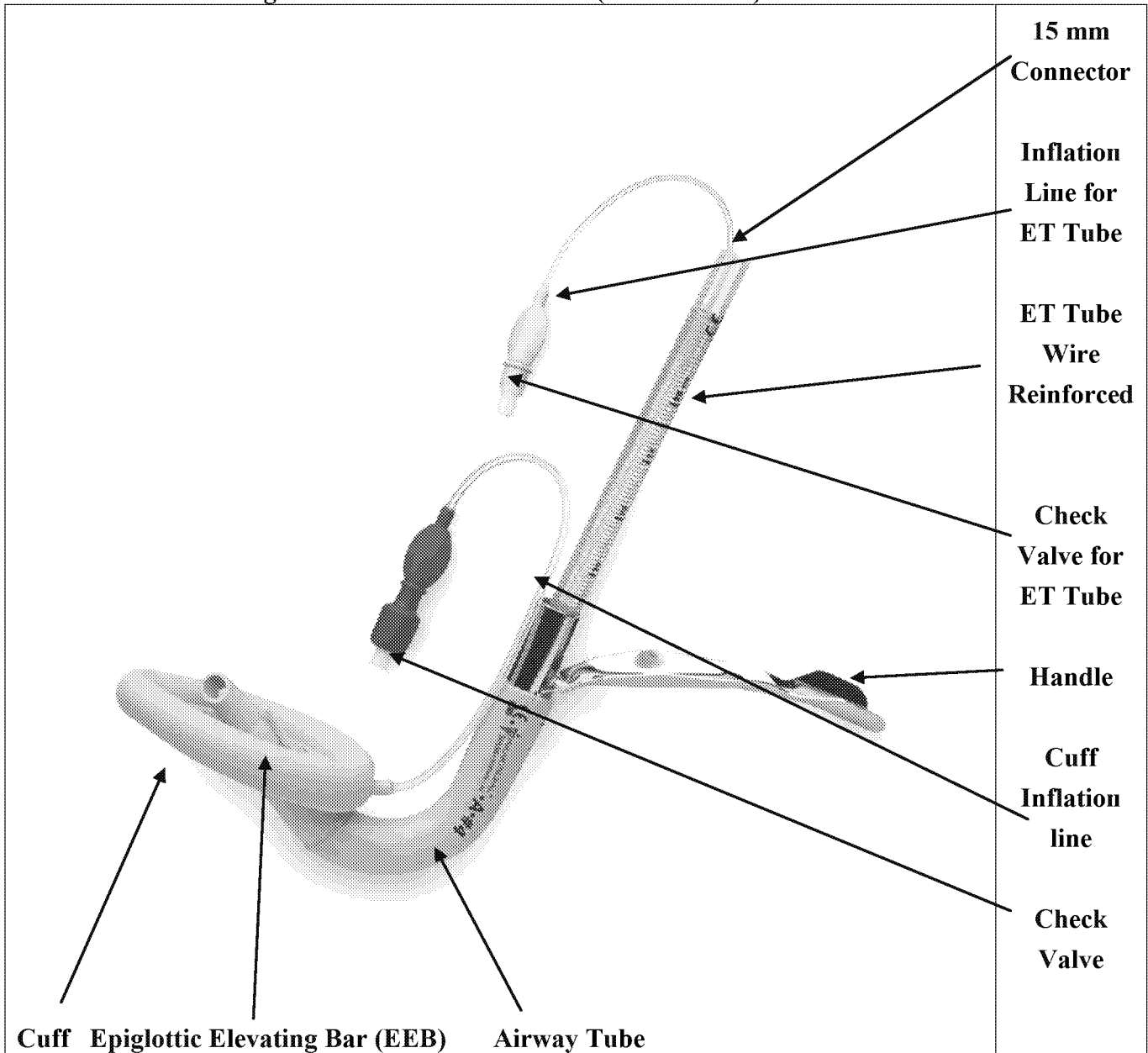


Figure 13.8 - LMA Fastrach™ ETT (reusable and single use)

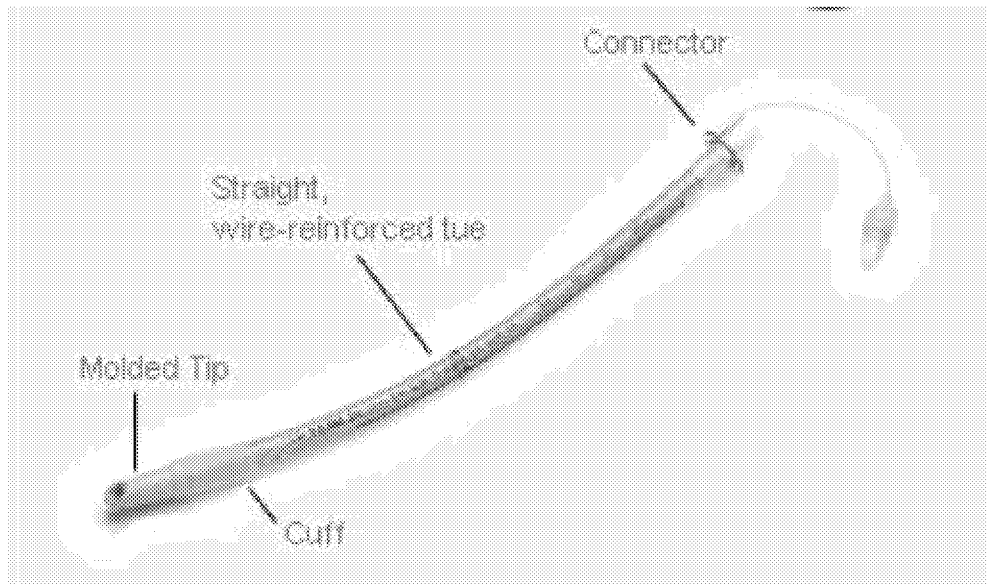
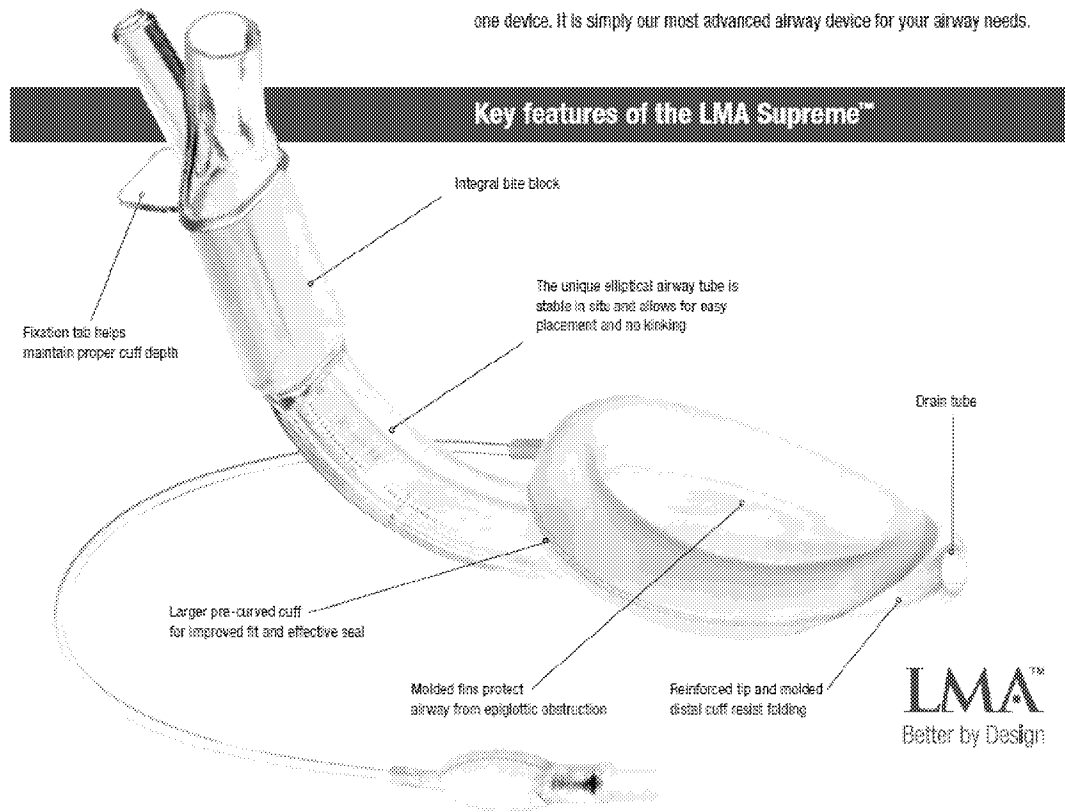


Figure 13.8 - LMA Supreme™



13.3 **Accessories and Kit Certification**

This submission is limited to seeking the MR Conditional environment of use indication.

There are no new or additional accessories for the LMA™ airway devices.

13.4 **Indications for Use**

(b)(4)

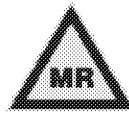
Supreme™ are devices inserted into a patient's pharynx through the mouth to provide a patent airway which can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

For the LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use

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.

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

We would be adding the required MR language to all instructions for use.



MR Conditional symbol per ASTM F2503-05

Non-clinical testing demonstrated that each product is MR Conditional and can be used in the MRI environment according to the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less

IMPORTANT NOTE: These products are intended for use inside of the MRI environment (e.g., in the MR system room). They will not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), during its operation (i.e., scanning). As such, the assessment of magnetic field interactions for these products specifically involved evaluations of translational attraction in relation to exposure to a 3-Tesla MR system, *only*.

13.5 **Contraindications**

There are new contraindications or changes from the predicates.

13.6 **Environments of Use**

Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

13.7 **Materials**

There have been NO changes in materials for any of the devices.

13.8 **Software**

There is no software operating these devices.

13.9 **Non-clinical Performance Testing**

We have performed testing in accordance to ASTM F2052-06e1. The performance testing for MR conditions is presented in **Section 20 – Performance Testing - Bench.**

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

(b)(4)

Fixation During Intended Use

(b)(4)

13.10 **Risk (Hazards) Analysis**

The addition of MR Conditional environment of use has been address in our risk assessment and testing performed to demonstrate that the devcies meet the performance and acceptable requirements for MR Conditional use.

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market The Laryngeal Mask Company LMA family of airways (K130304). We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4)

(b)(4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact me via email or at (240) 402-5121. If you need information or assistance concerning the IDE regulations, 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>.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sincerely yours,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

<u>11</u>	<u>Declarations of Conformity and Summary Reports</u>	<u>Page</u>
<u>11.1</u>	<u>Declaration of Conformity Standards (Form 3654)</u>	<u>2</u>

11.1 Declaration of Conformity Standards (Form 3654)

We have made a declaration of conformity to recognized standards in this submission and therefore Form 3654 Declarations of Conformity are attached.

In addition, there are no established performance standards under Section 514 which apply for the proposed device.

Premarket Notification 510(k)

LMA MR Conditional

Section 11 – Declarations of Conformity and Summary Reports

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filed in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION ☒ Traditional ☐ Special ☐ Abbreviated		
STANDARD TITLE ¹ ASTM F2052-06 Standard Test Method for Magnetically Induced Displacement Force		
Please answer the following questions		
Is this standard recognized by FDA? ²	Yes	No
	☒	☐
FDA Recognition number ³	# 8-124	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k)		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐
Title of guidance:		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360n], www.fda.gov/cdrh/sideprop.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html		

ORM FDA 3654 (9/87)

Page 1

JSC Quality (09-1404) Rev. 10/07

Section 11 – Declarations of Conformity and Summary Reports

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F2052-06 Standard Test Method for Magnetically Induced Displacement Force		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
No deviation		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

FORM FDA 3654 (9/07)

Page 2

Section 11 – Declarations of Conformity and Summary Reports

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)			
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).			
TYPE OF 510(k) SUBMISSION ☒ Traditional ☐ Special ☐ Abbreviated			
STANDARD TITLE ¹ ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment			
Please answer the following questions <table style="float: right;"> <tr> <th>Yes</th> <th>No</th> </tr> </table>		Yes	No
Yes	No		
Is this standard recognized by FDA? ²	☒ ☐		
FDA Recognition number ³	# 8-176		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒ ☐		
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒ ☐		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒ ☐		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒ ☐		
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐ ☒		
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	☐ ☒ ☐ ☐		
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐ ☒		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐ ☒		
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	☐ ☒ ☐ ☐		
Title of guidance:			
¹ The formatting convention for the title is: [SCO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360c]: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm ³ http://www.accessdata.fda.gov/scripts/cdrh/cdreh/510k/standards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); the test made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cdreh/510k/standards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm			

Section 11 – Declarations of Conformity and Summary Reports

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

<u>22</u>	<u>Performance Testing – Clinical</u>	<u>Page</u>
<u>22.1</u>	<u>Form 3674</u>	<u>2</u>

22.1 **Form 3674**

No clinical performance testing was performed with the proposed device. We have completed as attached Form 3674 as required.

See OMB Statement on Reverse, Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		
Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))		
(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)		
SPONSOR / APPLICANT / SUBMITTER INFORMATION		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER LMA North America	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 02/05/2013	
3. ADDRESS (Number, Street, State, and ZIP Code) 4660 LaJolla Village Dr., Suite 900 San Diego, CA 92122	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 919-433-8076 (Fax) 919-433-4996	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)		
LMA ProSeal™ LMA Classic™ LMA Fastrach™ Single Use LMA Fastrach™ ETT LMA Fastrach™ ETT Single Use LMA Flexible™ Single Use	LMA Classic Excel™ LMA Flexible™ LMA Supreme™ LMA Unique	
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other		
7. INCLUDE IND/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES		
CERTIFICATION STATEMENT / INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)		
☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.		
☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.		
☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)		
NCT Number(s):		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11	
(b)(6)	(Name) Elizabeth Paul	
	(Title) Director RA/QE Anesthesia / Respiratory	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 4624 Stirrup Creek Drive Durham, NC 27703	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 919-433-8076 (Fax) 919-433-4996	15. DATE OF CERTIFICATION 02/05/2013

FDA-3674 (1/08) (FRONT)

PSC Graphics (301) 443-1590 EP

Teleflex

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

MAY 27 2014

Received

Teleflex Incorporated
2917 Wack Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

May 23, 2014

K130304/5004

Re: K130304 – Response to Deficiency E-mail for LMA Airways for MR Conditional use

Dear Dr. Mendoza:

This is our response to the deficiencies raised during the interactive review of January 27th and subsequent e-mail of February 10th, 2014 for submission K130304.

eCopy STATEMENT

In accordance with section 745(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

I understand thank you.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [<mailto:drydenp@promedic.cc>]

Sent: Friday, May 30, 2014 1:16 PM

To: Mendoza, Mario

Subject: RE: K13030454 memo

Ok, but it will be about 1 hour before I can get to it. On a conference call

(b)(4)

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

M - (b)(6)

F - +239-236-0354

E - drydenp@promedic.cc

Web - www.promedic.cc

Twitter - <https://twitter.com/ProMedicInc>

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From: Mendoza, Mario [<mailto:Mario.Mendoza@fda.hhs.gov>]

Sent: Friday, May 30, 2014 1:14 PM

To: Paul Dryden

Subject: K13030454 memo

(b)(4)

Thanks and sorry about all of this back and forth,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney, Todd D
Sent: Friday, May 30, 2014 11:50 AM
To: Mendoza, Mario
Subject: RE: K130304S4 memo

(b)(5)

From: Mendoza, Mario
Sent: Friday, May 30, 2014 10:54 AM
To: Courtney, Todd D
Subject: K130304S4 memo

(b)(5)

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/OCE/DAGRID/ANDB
W066, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Courtney, Todd D
Sent: Friday, May 30, 2014 10:35 AM
To: Mendoza, Mario
Subject: RE: K130304S4 for (b)(5)

(b)(5)

From: Mendoza, Mario
Sent: Friday, May 30, 2014 9:52 AM
To: Courtney, Todd D
Subject: RE: K130304S4 for (b)(5)

(b)(5)

Thanks,
M

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/OCE/DAGRID/ANDB
W066, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Courtney, Todd D
Sent: Thursday, May 29, 2014 9:22 PM
To: Mendoza, Mario
Subject: RE: K130304S4 (b)(5)

(b)(5)

Thanks,

Todd

From: Mendoza, Mario
Sent: Thursday, May 29, 2014 4:14 PM
To: Courtney, Todd D
Subject: RE: K130304S4 (b)(5)

Thanks Todd,

(b)(5)

M

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/OCE/DAGRID/ANDB
W066, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Courtney, Todd D
Sent: Thursday, May 29, 2014 10:30 AM
To: Mendoza, Mario
Subject: RE: K130304S4

(b)(5)

Hi Mario,

(b)(5)

Thanks,

Todd

From: Mendoza, Mario
Sent: Wednesday, May 28, 2014 2:29 PM
To: Courtney, Todd D
Subject: K130304S4

(b)(5)

Hi Todd,

(b)(5)

Thanks for your review,
Mario

K 130304/5002

Teleflex

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center -- WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

SEP 05 2013

Received

Teleflex Incorporated
2511 Wisp Drive
P.O. Box 12800
Research Triangle Park
NC 27709
USA
www.teleflex.com

September 4, 2013

Subject: K130304 -- Response to Refuse to Accept for LMA Airways for
MR Conditional use

Dear Dr. Mendoza:

This is response to the Refuse to Accept e-mail of 9/4/13 for K130304.

eCopy STATEMENT

In accordance with Section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission.
It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency as presented in the "Comments" section of the Refuse To Accept Checklist.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

26

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Wednesday, January 29, 2014 5:20 PM
To: Mendoza, Mario
Subject: RE: K130304/S003

Dr, Mendoza

Thank you for this, I will review with Teleflex.

I take note on the extension to respond of COB 2/3.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
F - + 239-236-0354
E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>
Web - www.promedic.cc<http://www.promedic.cc/>

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Wednesday, January 29, 2014 5:17 PM
To: Paul Dryden
Subject: K130304/S003

Dear Mr. Dryden:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Dear Mr. Dryden:

(b)(4)

(b)(4)

Please provide your response to the above deficiencies via email to me close of business January 31, 2014.

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Teleflex Incorporated
2917 Weck Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

May 23, 2014

Re: K130304 – Response to Deficiency E-mail for LMA Airways for MR Conditional use

Dear Dr. Mendoza:

This is our response to the deficiencies raised during the interactive review of January 27th and subsequent e-mail of February 10th, 2014 for submission K130304.

eCopy STATEMENT

In accordance with section 745(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment # 1

LMA Unique Size 5 Bspak Valve During and Post MRI Test

**DESIGN VERIFICATION PROTOCOL
LMA Unique Size 5 Bespak Valve MRI Test
Summary Report**

(b)(4)

For Use by Affiliates of Teleflex

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Approvals and Form History on file in Teleflex Document Control Center RTP. Form Issue Date: 14 Feb 2014

Questions? Contact FDA/CDRH/OCE/DPL/CDRH-FOI@FDA or 301-796-8118

(b)(4)

Attachment # 5A

LMA Fastrach reusable Instructions for use with MR Unsafe

English

Instructions for Use – LMA Fastrach™, LMA Fastrach™ Single Use, LMA Fastrach™ ETT & LMA Fastrach™ ETT Single Use

Caution: Federal (U.S) law restricts this device to sale by or on the order of a physician

Device Description:

LMA Fastrach™
The intubating LMA airway
The LMA Fastrach™ is designed to facilitate blind intubation without moving the head or neck and allowing for single handed insertion. The LMA Fastrach™ allows continuous ventilation between intubation attempts.

The LMA Fastrach is supplied in a sterile version for single use only as well as in a non-sterile version which must be cleaned and sterilized before initial use and before each subsequent use. The non-sterile version may be used a maximum of 40 times before being discarded. Both the single use and reusable LMA Fastrach™ are not made with natural rubber latex.

LMA Fastrach™ ETT

The LMA Fastrach™ Endotracheal Tube (ETT) has been developed specifically for use with the LMA Fastrach™. It is a straight, wire-reinforced silicone, cuffed endotracheal tube capable of being passed entirely through the LMA Fastrach™. The size of the pilot balloon and placement of the inflation line facilitate passage through the LMA Fastrach. The tip is made out of a radio opaque material so it is more visible in x-rays.

The LMA Fastrach™ ETT is supplied in a sterile version for single use only as well as in a non-sterile version which must be cleaned and sterilized before initial use and before each subsequent use. The non-sterile version may be used a maximum of 10 times before being discarded. Both the single use and reusable LMA Fastrach™ ETT are not made with natural rubber latex.

Intended Use:

The LMA Fastrach™ is indicated for use in achieving and maintaining control of the airway during anticipated (1) or unanticipated (1) difficult airways and emergency anesthetic procedures using either spontaneous (2) or Positive Pressure Ventilation (PPV) (3). LMA Fastrach™ is also intended for use as a rescue device in emergency situations. (2, 1, 4, 5)

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 (2, 6, 7).

Indications for Use:

- The LMA Fastrach™ is indicated for use as a guide for intubation of the trachea (2, 6, 7).
- The LMA Fastrach™ is indicated for achieving and maintaining control of the airway during routine and emergency situations, including anticipated or unexpected difficult airways (2, 1, 4, 5).
- The LMA Fastrach™ is indicated as a method of establishing an airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

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 (2, 6, 7).

Risk-Benefit Information

When used in the profoundly unresponsive patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e., "cannot intubate, cannot ventilate"), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway.

Contraindications:

The use of the LMA as a substitute for an endotracheal tube is not recommended in the following elective or difficult airway patients on a non-emergency pathway:

LMA Fastrach™ Airway

1. Non-fasted patients, including patients whose fasting cannot be confirmed and in other situations where there may be retained gastric contents.
2. Patients who are, more than 14 weeks pregnant, or those with any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.
3. Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis or because the peak airway inspiratory pressures are anticipated to exceed 20 cm H₂O.
4. Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history.
6. Patients in the prone position.
7. Patients who are not profoundly unconscious and who may resist device insertion.
8. Intubation through the device is contraindicated in the presence of oesophageal or pharyngeal pathology.
9. The reusable LMA Fastrach™ should not be used in patients eligible for magnetic resonance imaging (MRI) investigation.

Contraindications (Continued)

1. The LMA Fastrach™ ETT should not be placed in patients eligible for procedures which involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device.

Adverse Effects:

There are reported adverse reactions associated with the use of laryngeal mask airways and endotracheal tubes. Standard textbooks and published literature should be consulted for specific information.

Warnings:

1. LMA Fastrach™ and LMA Fastrach™ ETT are supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.
 2. LMA Fastrach™ Single Use (LMA Fastrach™ SU) and LMA Fastrach™ ETT Single Use (LMA Fastrach™ ETT SU) are supplied sterile for single use. Do not re-sterilise and/or reuse the LMA Fastrach™ SU and Fastrach™ ETT SU. The device is provided sterile and should be used straight from the package and is not designed to withstand reuse, cleaning or exposure to disinfecting or sterilizing agents.
 3. The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.
 4. The use of a standard, curved, plastic ETT in conjunction with LMA Fastrach™ is not recommended as it may be associated with increased likelihood of laryngeal trauma.
 5. The rigid tube and handle of the LMA Fastrach™ may make it unsuitable as the sole airway in cases where the head needs to be turned to the side or in cases where the patient is in the prone position.
 6. Do not cut the LMA Fastrach™ ETT.
 7. If a malleable stylet is used in the LMA Fastrach™ ETT during intubation, ensure that it does not protrude from the patient end or Murphy Eye of the tube.
 8. Do not overinflate the cuff of the LMA Fastrach™ ETT as this can result in rupture and subsequent deflation, or cuff distortion, which may lead to airway blockage and/or patient injury.
 9. Deflate LMA Fastrach™ ETT cuff prior to repositioning ETT. Movement of the ETT with the cuff inflated could result in patient injury or cuff damage.
 10. Never over-inflate the cuff over 60cm H₂O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
 11. To avoid trauma, excessive force should not be used at any time when using the LMA Fastrach™.
 12. A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the LMA airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reactions, or may affect the surrounding structures, including the vocal cords.
 13. For reusable products, do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex), ethylene oxide, phenol-based cleaners or iodine-containing cleaners to clean or sterilize the LMA airway. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.
 14. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.
 15. Ensure that the patient is anesthetized, paralyzed and pre-oxygenated. Inadequate anesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the ETT into the larynx.
 16. If the LMA Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H₂O pressure. This low pressure stabilizes the airway in the pharynx. Avoid unnecessary movement of the device and maintain head or neck in a neutral position.
 17. Displacement of the LMA Fastrach™ ETT (esophageal intubation, accidental extubation) may occur if the LMA Fastrach™ removal procedure is not performed correctly. In these cases a correctly deflated LMA Fastrach™ should be re-inserted without delay to ensure patient oxygenation.
- Precautions:**
1. An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.
 2. Careful handling is essential. Avoid contact with sharp or pointed objects at all times to prevent tearing or perforation of the device.
 3. When passing a fiberoptic bronchoscope (FOB), it should not be passed through the LMA Fastrach™ airway aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottis elevating bar.
 4. When selecting seal pressure for the ETT, an intracuff pressure measuring device should be used in conjunction with the Minimal Occluding Volume, or Minimum Leak techniques. Cuff inflation should be monitored continuously to a "just seal" pressure. Any deviation from the selected seal pressure should be investigated and corrected immediately.

5. The use of aerosolized lidocaine has been associated with the formation of pharyngeal secretions. Do not use LMA Fastrach™™ ETT SU cuffs.
6. Use only ventilators or anesthesia equipment with standard 15mm connectors to ensure secure connection with the ETT connector. Always ensure that the connector is securely seated in the breathing circuit to prevent disconnection during use.
7. Three-way stopcocks, or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve causing the cuff to deflate.
8. Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. To blunt such diffusion, it is recommended that the cuff be inflated with the same gas mixture that contacts the cuff's external surface.
9. Laryngeal spasm may occur if the patient becomes too lightly anaesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, do not remove the LMA™ airway, but treat the cause.
10. Only remove the device when airway protective reflexes are fully competent.
11. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention.
12. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
13. Used reusable device shall be decontaminated first in accordance with local hospital procedures for handling biohazard products and subsequently disposed of by incineration or landfill in accordance with local and national regulations.
14. Do not use a device if it is damaged or the unit packaging for LMA Fastrach™ SU and LMA Fastrach™ ETT SU is damaged or opened.
15. The LMA airway does not always protect against regurgitation or aspiration. Its use in anesthetized patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anesthesia. Do not use the device without taking appropriate precautions to ensure the stomach is empty.
16. Gloves should be worn during preparation and insertion to minimize contamination of the device.
17. If airway problems persist or ventilation is inadequate, the LMA Fastrach™ should be removed and an airway established by some other means.
18. The LMA Fastrach™™ is not indicated for use as an alternative to the endotracheal tube (ETT).
19. It is most important that pre-use checks are carried out on LMA airway prior to use, in order to establish whether they are safe for use. Failure of any one test indicates the device should not be used.
20. When applying lubricant avoid blockage of the airway aperture with the lubricant.
21. For LMA Fastrach™ ETT, gently fit the connector into the LMA Fastrach™ ETT prior to applying lubricant to the distal end of the tube. Excessive amounts of lubricant may cause partial or full blockage of the lumen and airway which may cause a risk of aspiration.
22. Ensure all removable denture work is removed before inserting the device
23. Never use the handle of LMA Fastrach™™ to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult
24. Use caution when using the LMA Fastrach™™ during a procedure where the patient's head needs to be turned to the side during the case.

Preparation for Use:

Choose the correct size of LMA Fastrach™™ & LMA Fastrach™™ SU
Patient Weight/Size

- Size 3: 30kg – 50kg pediatric/adult
- Size 4: 50kg – 70kg adult
- Size 5: 70kg – 100kg adult

Compatibility of LMA Fastrach™™ ETT & LMA Fastrach™™

LMA Fastrach™™ ETT and LMA Fastrach™™ ETT SU are available in a variety of sizes and can be used conventionally as an endotracheal tube.

All sizes (6, 6.5, 7, 7.5 and 8) of reusable LMA Fastrach™™ ETT are compatible with LMA Fastrach™™ and LMA Fastrach™™ SU. However, only size 6, 6.5 and 7 of LMA Fastrach™™ ETT SU are compatible with LMA Fastrach™™™ and LMA Fastrach™™™ SU.

Caution: Clinical judgment should be used in the selection of the appropriate device size for an individual patient.

Pre-Use Checks:

It is most important that pre-use checks are carried out on LMA airways prior to use, in order to establish whether they are safe for use. **Warning:** Failure of any one test indicates the device should not be used.

For LMA Fastrach™™:

These tests should be carried out as follows:

1. **Examine the interior and exterior of the airway tube** to ensure it is free from blockage or loose particles. Examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. **Examine the angle** between the straight part of the airway tube and the anterior plane of the inflated cuff. The angle should never exceed 90 degrees.
3. **Examine the Epiglottis Elevating Bar (EEB).** Gently probe the flexible EEB traversing the mask aperture to ensure the free end of the bar lies in contact with the mask and is not broken or damaged. Do not use if the EEB is not intact and positioned correctly as the epiglottis may obstruct the airway. Do not attempt to remove or repair a broken/damaged bar.
4. **Deflate the cuff fully.** Ensure that the anterior and posterior cuff walls are tightly flattened against each other. Discard if cuff reinflates immediately or spontaneously, even if only slightly, indicating possible damage to device or valve.
5. **Overinflate the Cuff.** Reinflate the device with a volume of air 50% greater than the maximum inflation value for each size.

- Size 3 30ml Pediatric/Adult
- Size 4 45ml Adult
- Size 5 60ml Adult

Keep a clearly marked syringe for inflation and deflation of the cuff.

Examine the cuff for leaks, herniations and uneven bulging. If any indication of these, discard the device. A herniated cuff may cause obstruction during use. While the device remains 50% over-inflated, examine the inflation pilot balloon and inflation line. The balloon shape should be elliptical, not spherical or with any bulges.

For LMA Fastrach™ ETT:

1. Deflate the cuff completely then fully inflate the valve and cuff to test their integrity. Do not overinflate the cuff.
2. Visually check that the airway tube, cuff and balloon are free of debris and leaks, and are not damaged, kinked, nor occluded. Do not use if the device doesn't inflate symmetrically, shows sign of deterioration/abnormality or if there is a deficiency with the inflation mechanism.
3. Ensure that the connector is attached into the LMA Fastrach™ ETT.

Pre-insertion Preparation:

Deflate completely: Deflate the LMA Fastrach™ by using the syringe or LMA Cuff Deflator to create a fully deflated and smooth leading edge, facilitating insertion and avoiding contact with the epiglottis.

Warning: For LMA Fastrach™, lubricate only the posterior surface of the deflated mask tip. Do not lubricate the front as this may result in blockage of the EEB or aspiration of lubricant.

Warning: For LMA Fastrach™ ETT, gently fit the connector into the LMA Fastrach™ ETT prior to applying lubricant to the distal end of the tube. Excessive amounts of lubricant may cause partial or full blockage of the lumen and airway which may cause a risk of aspiration.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA Fastrach™ & LMA Fastrach™ ETT components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

Warning: Ensure all removable denture work is removed before inserting the device.

Insertion (for LMA Fastrach™)

Caution: gloves must be worn

Warning: Do not apply excessive force to the LMA Fastrach at any time during use.

1. Anaesthesia must be deep enough or with adequate pharyngeal topicalisation to permit insertion.
2. Position the head in a neutral position, with a pillow under the head. Do not extend the head.
3. Hold LMA Fastrach™ by its handle, approximately parallel to the patient's chest. Position the mask tip against the hard palate and slide the tip briefly back and forth to distribute the lubricant and prevent folding of the tip, before sliding the mask further backwards following the curve of the rigid airway tube (Fig.1). Do not use the device handle as a lever to force the mouth open.
4. Advance (without rotation) the curved airway tube until the straight part of the airway tube is in contact with the chin. Rotate the mask into place in a circular movement, ensuring pressure is maintained against the soft palate and posterior pharynx (Fig.2).
- Warning:** Never use the handle to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult.
5. After insertion, check that the tube emerging from the mouth is parallel to the plane of the inner surface of the upper incisors.
6. Inflate the cuff to a pressure of approximately 60 cm H₂O, not exceeding the maximum inflation volume.
- Warning:** Never overinflate the cuff.

Maximum inflation volumes (ml)

Size 3	20ml
Size 4	30ml
Size 5	40ml

7. Connect to the anaesthetic system. Exercise care to prevent dislodgement of the device.
8. Stabilize the device in neutral position (e.g. with bilateral bite blocks) to minimize head or neck movement. Bite block should be removed prior to intubation to allow adjustment of LMA Fastrach™ position.
- Warning:** If the LMA Fastrach™ is the sole airway, it is very important to monitor cuff pressure and to ensure that the device is stabilized in a neutral position to prevent unnecessary movement.



Figure 1



Figure 2

Intubation:

Below describes various methods of intubation using LMA Fastrach™ ETT with and without an assisting device. It is recommended to use LMA Fastrach™ with LMA Fastrach™ ETT for optimal intubation. LMC will not be liable for use of an inappropriate ETT.

Caution: If LMA Fastrach™ is used, ensure it is properly positioned before attempting intubation.

Warning: Ensure that the patient is anaesthetized, paralyzed and pre-oxygenated. Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the ETT into the larynx.

Tracheal Intubation with the LMA Fastrach™

1. Pass the ETT into the LMA Fastrach™ airway tube and distribute the lubricant within the shaft by moving the ETT up and down until it travels freely through the entire airway tube.
2. Position the longitudinal line of ETT to face the LMA Fastrach™ handle. Gently insert the ETT into the device airway tube. ETT should not pass beyond the 15 cm transverse depth marker. Ensure that the tip of the ETT does not enter the mask aperture (Fig.3).

3. Grip the handle firmly and lift the device using the handle to draw the airway tube forward, lifting the ETT and aligning the ETT axes (Fig.4).
4. Slide the ETT gently into the LMA Fastrach™ another 1.5cm past the 15cm mark. If no resistance is felt, continue to advance the ETT while holding the device steady until intubation is accomplished.
5. Inflate the cuff of the ETT.
6. Confirm intubation by conventional means (e.g. end tidal CO₂).

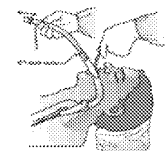


Figure 3



Figure 4

Intubation with LMA Fastrach™ and with Fiberoptic Bronchoscope (FOB) Assistance

1. Attach a self-sealing connector with a suitable side-arm through the ETT to permit continued ventilation.
2. Select an FOB of an appropriate diameter and length to pass within the ETT. When fully inserted, the FOB should not protrude through the end of the assembled ETT and sealing port. It should also not pass beyond the EEB of LMA Fastrach™ unless protected by the ETT. Otherwise its tip may be deviated or damaged by the EEB.
3. Insert the ETT up to 15cm depth, verify with the FOB that the ETT tip contacts the EEB of the device.
4. At 16.5cm depth, verify with the FOB that the ETT lifts the EEB showing the glottis.
5. Advance the ETT into the trachea; avoid pushing on the EEB with the FOB.
6. Inflate the cuff of the ETT.

Conventional tracheal intubation with LMA Fastrach™ ETT under direct or indirect laryngoscopy

The LMA Fastrach™ ETT is designed to be used conventionally as an endotracheal tube.

Warning: Always use an aseptic technique.

1. Intubate using currently accepted medical techniques. A lubricated male intubation stylet may need to be used due to the flexibility of the airway tube of the ETT.
2. Inflate the cuff with the minimum amount of gas mixture to provide an effective seal at the desired lung inflation pressure. Using minimal Occluding Volume and Minimum Leak Techniques along with routine monitoring of intracuff pressure may reduce the occurrence of many adverse reactions associated with the use of cuffed endotracheal tubes.
3. Remove the luer-tip syringe from the valve.
4. Check ETT placement by confirming breathing sounds and monitoring end-tidal CO₂.
5. Connect ETT to the anaesthesia or ventilator circuit.
6. Securely anchor the ETT using a bite block to avoid unnecessary movement or damage.
7. Monitor cuff pressure continuously.

Removal of the LMA Fastrach™ after tracheal intubation

Warning: There are reports of pharyngeal oedema and increased mucosal pressure attributed to the rigidity of the airway tube. It is recommended to remove LMA Fastrach™ once intubation has been accomplished. High pressures may develop against the pharyngeal wall if the head or neck is moved from the neutral position, due to the rigidity of the curved airway tube. The risk of maintaining in place the LMA Fastrach™ must be weighed against the potential risks associated with the manoeuvre of removal of the device.

Warning: If the LMA Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H₂O pressure. This low cuff pressure stabilizes the airway in the pharynx. Avoid unnecessary movement of the device and maintain head or neck in a neutral position.

Warning: Displacement of the LMA Fastrach™ ETT (oesophageal intubation, accidental extubation) may occur if the LMA Fastrach™ removal procedure is not performed correctly. In these cases a correctly deflated LMA Fastrach™ should be reinserted without delay to ensure patient oxygenation.

1. Using the LMA™ Stabiliser Rod, measure the approximate distance between the proximal end of the ETT and the patient's teeth.
2. After ensuring that the patient is well oxygenated, disconnect the circuit leaving the ETT connector attached. Fully deflate the LMA Fastrach™ cuff, making sure the ETT cuff remains inflated.
3. Gently tap or swing the device handle caudally around the chin. Using curvature of the airway tube, slide the device out of the pharynx into the oral cavity, applying counter pressure to the ETT with the finger (Fig.5).
4. When the proximal end of the ETT is level with the proximal end of the airway tube, remove the ETT connector and insert the stabilizer rod to keep the ETT in place. While holding the stabilizer rod, slide out the LMA Fastrach™ over the ETT and stabilizer rod until it is clear of the mouth. (Fig.6)
5. Remove the stabilizer rod when the LMA Fastrach™ cuff is clear of the mouth while holding the ETT in place to prevent accidental dislodgment (Fig.7). Grasp the ETT firmly while gently unthreading the inflation line and pilot balloon from the LMA Fastrach™ tube (Fig.8).
- Caution:** Failure to remove the stabilizer rod from airway tube before completely removing the LMA Fastrach™ may result in the ETT being accidentally pulled out or the pilot balloon or inflation line tubing being damaged.
6. Using the stabilizer rod, check the position of the ETT by measuring the distance of the proximal end from the teeth. If, during removal of the LMA Fastrach™, any displacement of the ETT has occurred, an appropriate adjustment will need to be made.
7. Replace the ETT connector and ventilate the patient.
- Caution:** Verify correct tube placement and patient oxygenation immediately after LMA Fastrach™ removal, or if the patient's position is altered after intubation.

8. ETT should be securely anchored using a bite-block to avoid unnecessary movement or damage.

In elective cases, after removal, LMA Fastrach™ may be re-inserted behind the ETT to provide an immediate airway if deep extubation is planned or extubation is clinically determined to be hazardous.



Figure 5



Figure 6

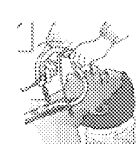


Figure 7

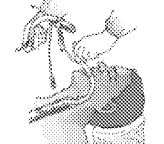


Figure 8

Removal of the LMA Fastrach™ ETT

Clinical judgment should be used to determine how long LMA Fastrach™ ETT is to remain in the patient.

1. Immediately prior to extubation or repositioning of the ETT, completely deflate the cuff using a syringe.
2. Extubate using currently accepted medical techniques.

Cleaning reusable LMA Fastrach™ & LMA Fastrach™ ETT:

Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Endozime® (Ruhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilise LMA Fastrach™ and LMA Fastrach™ ETT. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.

Caution: Do not expose the valve (the white plastic piece protruding from the inflation balloon) to any cleaning solution as it may cause premature valve failure.

If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm flowing tap water, remove excess moisture, and allow it to dry. If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Clean the LMA Fastrach™ using a small soft bristle brush (approximately 17mm in diameter). Gently insert the brush through the EEB bars into the airway tube, taking care not to damage the bars. Ensure the whole interior of the metal tube is thoroughly cleaned.

Thoroughly rinse the device in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

Warning: Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.

Sterilizations of reusable LMA Fastrach™ & LMA Fastrach™ ETT

Immediately prior to steam autoclaving, deflate the cuff completely. Ensure both the syringe (used to deflate the cuff) and the valve are dry.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon. To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port after deflation.

If a deflated mask immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the LMA airway, provided that the maximum autoclave temperature does not exceed 137°C or 278.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

Caution: The integrity of the LMA™ Fastrach airway materials may be adversely affected by exceeding sterilization temperatures of 278.6°F or 137°C.

Autoclaves vary in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare personnel are responsible for adhering to the appropriate sterilization processes which have been specified. Failure to do so may invalidate the sterilization process of the healthcare facility.

After autoclaving, allow the device to cool to room temperature before use.

MRI Information



MR Conditional

The LMA Fastrach (Single Use), Fastrach ETT and Fastrach ETT SU are MR Conditional. Non-clinical testing demonstrated that these products are MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence).

Note: The LMA Fastrach (Reusable) is MR Unsafe.

MRI-Related Heating

Under the scan conditions defined above, all LMA devices are expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 90-mm relative to the size and shape of the LMA Fastrach, ETT Size 8 and approximately 20-mm relative to the size and shape of the LMA Supreme, Size 5 which is representative of the LMA Fastrach SU.

Symbol Definition:

	Manufacturer
	Authorized representative in the European Community
	Consult Instructions For Use on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	Serial Number
	Do not Re-use
	Do not re-use more than 10 times
	Do not reuse more than 40 times
	Non-sterile
	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)

	Use By
	Do not use if package is damaged

References

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Manufacturer's Warranty:

The LMA Fastrach™ is reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

The LMA Fastrach™ ETT is reusable and warranted against manufacturing defects for ten (10) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

The LMA Fastrach™ Single Use and LMA Fastrach™ ETT Single Use are designed for single patient use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.



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Issue: PMS-2100-003 Rev E UK

Attachment # 5B

Instructions for Use revised to include Classic Excel



The Laryngeal Mask Company Limited

English

Instructions for Use – LMA Classic™, LMA Classic Excel™, LMA Flexible™, LMA Flexible™ Single Use & LMA Unique™

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician

Device Descriptions:

LMA Classic™

The first LMA airway

The LMA Classic™ is reusable general purpose airway for elective and emergency procedures. LMA Classic™ consists of three main components made primarily of medical grade rubber: an airway tube, cuff and inflation line. The airway is a large-bore tube with a 15mm connector on the proximal end. The distal end is fitted with an elliptical cuff which is inflated and deflated via a valve on the end of the inflation line. The mask is designed to conform to the contours of the hypopharynx with its lumen facing the laryngeal openings and covering supraglottic structures.

The LMA Classic™ is supplied non-sterile and must be cleaned and sterilized before initial use and each subsequent use. It may be used a maximum of 40 times before being discarded. The LMA Classic™ is not made with natural rubber latex.

LMA Classic Excel

LMA Classic with Extended Benefits

The LMA Classic Excel is a specialized version of the LMA Classic. The Classic Excel features a removable connector at the end of the airway tube and an epiglottic elevating bar on the anterior surface of the mask allow an endotracheal tube or gastric tube to be placed while the Classic Excel remains in place.

The LMA Classic™ Excel is supplied non-sterile and must be cleaned and sterilized before initial use and each subsequent use. It may be used a maximum of 60 times before being discarded. The LMA Classic™ Excel is not made with natural rubber latex.

LMA Unique™

The Single-Use LMA Classic™

LMA Unique™ is used for the same indications as the LMA Classic™. It is differentiated by having a PVC cuff and is supplied sterile for single-use only. The LMA Unique™ can be used for a wide range of routine applications ranging from general anesthesia to emergency use or as a resuscitation device. The LMA Unique™ is not made with natural rubber latex.

LMA Flexible™

For Head and Neck Surgery

LMA Flexible™ is differentiated from other LMA airways by having a flexible wire-reinforced airway tube that allows it to be positioned away from the surgical field. It may be particularly useful in procedures where the surgeon and anesthesiologist are working in the same area, such as procedures involving the head or neck. The flexibility of the airway tube provides an easy connection at any angle from the mouth and allows the tube to be repositioned from the side during the surgical procedure without loss of seal of the cuff against the larynx.

The LMA Flexible™ is supplied in a sterile version for single-use as well as in a non-sterile version which must be cleaned and sterilized before initial use and each subsequent use. The non-sterile version may be used a maximum of 40 times before being discarded. The LMA Flexible™ is not made with natural rubber latex.

Intended Use:

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 (1, 2) and emergency procedures (3) using either spontaneous or Positive Pressure Ventilation (PPV).

Indications for Use:

- An alternative to a face mask (4)
- An airway device in routine anesthesia procedures (2)
- Securing the immediate airway in anticipated or unexpected difficult airway situations. (3)
- Use in elective surgical procedures where tracheal intubation is not necessary. (5, 6, 1)
- Establishing an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient requiring artificial ventilation when tracheal intubation is not possible (7, 8, 9, 10, 11)

Risk-Benefit Information:

When used in the profoundly unresponsive patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e., "cannot intubate, cannot ventilate"), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway. (7)

Contraindications:

The use of the LMA as a substitute for an endotracheal tube is not recommended in the following elective or difficult airway patients on a non-emergency pathway:

- Non-fasted patients,
- Patients whose fasting cannot be confirmed

• Any situation where there may be retained gastric contents.

- Patients more than 14 weeks pregnant
- Emergency and resuscitation situations
- Any condition associated with delayed gastric emptying
- Patients using opiate medication prior to fasting,
- Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 20 cm H₂O,
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history.
- Patients who are not profoundly unconscious and who may resist device insertion.

Adverse Effects

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks and published literature should be consulted for specific information.

Warnings:

1. LMA Classic™, LMA Classic Excel and LMA Flexible™ are supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.
2. LMA Unique™ and LMA Flexible™ Single Use (LMA Flexible™ SU) are supplied sterile for single use only and shall be discarded after use and must not be re-used. The use of products intended for single patient use on more than one patient may result in degraded performance or loss of functionality and may also result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these products. This product is not designed to be cleaned, disinfected or sterilized.
3. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.
4. To avoid trauma, do not apply excessive force to the LMA Airways at any time during use.
5. The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily (typically less than 24 hours) with pregnant women, nursing mothers, babies and infants.
6. Never inflate the cuff over 60cm H₂O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
7. A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the LMA airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.
8. For reusable products (LMA Classic™ and LMA Flexible™), do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex), ethylene oxide, phenol-based cleaners or iodine-containing cleaners to clean or sterilize the LMA airway. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.

Precautions:

1. LMA airways do not always protect regurgitation or aspiration. Its use in anesthetized patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anesthesia. Do not use the device without taking appropriate precautions to ensure the stomach is empty.
2. Laryngeal spasm may occur if the patient becomes too lightly anaesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, do not remove the LMA airway, but treat the cause.
3. Only remove the device when airway protective reflexes are fully competent.
4. Do not pull or use undue force when handling the inflation line or try to remove the device from patient by the inflation tube as it may detach from the cuff spigot.
5. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention.
6. Use only syringe with standard luer taper tip for inflation or deflation.
7. Do not immerse or soak single use devices (LMA Flexible™ SU & LMA Unique™) in liquid prior to use.
8. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
9. Used reusable devices (LMA Classic™, LMA Classic Excel & LMA Flexible™) should be decontaminated first in accordance with local hospital procedures for handling of bio-hazard products and

subsequently disposed of by incineration or landfill in accordance with local regulations.

10. Do not use if the device is damaged or the packaging is damaged or opened.
11. Gloves should be worn during preparation and insertion to minimize contamination of the device.
12. If airway problems persist or ventilation is inadequate, the LMA Airway should be removed and an airway established by some other means.
13. When applying lubricant avoid blockage of the airway aperture with the lubricant
14. Careful handling is essential. The LMA Unique™ and LMA Flexible™ SU are made of medical grade PVC which can be torn or perforated. Avoid contact with sharp or pointed objects at all times. Do not insert the device unless the cuff is fully deflated as described in the instructions for insertion.
15. Ensure all removable denture work is removed before inserting the device.
16. It is most important that pre-use checks are carried out on LMA airway prior to use, in order to establish whether they are safe for use. Failure of any one test indicates the device should not be used.
17. For reusable products, do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.
18. For reusable products, immediately prior to steam autoclaving, deflate the cuff completely. Any air or moisture left in the cuff will expand at the high temperature and low pressure of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.
19. The integrity of the reusable LMA airway materials may be adversely affected by exceeding sterilization temperature of 137°C or 278.6°F
20. It is important that pre-use checks are carried out on LMA airways prior to use, in order to establish whether they are safe for use. Failure of any one test indicates the device should not be used.

Preparation for Use:

Choose the correct size of LMA™ airway

Patient Weight/Size

1: up to 5kg Neonatal	3: 30kg - 50kg Pediatric/Adult
1½: 5kg - 10kg Pediatric	4: 50kg - 70kg Adult
2: 10kg - 20kg Pediatric	5: 70kg - 100kg Adult
2½: 20kg - 30kg Pediatric	6: >100kg Adult

Keep a clearly marked syringe for inflation and deflation of the cuff.

Pre-Use Checks

It is most important that pre-use checks are carried out on LMA™ airways prior to use, in order to establish whether they are safe for use. **Warning:** Failure of any one test indicates the device should not be used.

These tests should be carried out as follows:

1. **Examine the interior of the airway tube** to ensure it is free from blockage or loose particles. Examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. **Holding at each end flex the airway tube** to increase its curvature up to but not beyond 180°. Should the tube kink during this procedure, discard the device.
3. **Deflate the cuff fully.** Re-inflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 1	6ml	Size 3	30ml
Size 1½	10ml	Size 4	45ml
Size 2	15ml	Size 5	60ml
Size 2½	21ml	Size 6	75ml

Examine the cuff for leaks, herniations and uneven bulging. If there is any indication of these, discard the device. A herniating mask may cause obstruction during use. Then deflate the mask again. While the device remains 50% over-inflated, examine the blue inflation pilot balloon. The balloon shape should be elliptical, not spherical.

4. **Examine the airway connector.** It should fit securely into the airway tube and it should not be possible, using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
5. **Discoloration.** Discoloration affects visibility of fluid in the airway tube.
6. Gently pull the inflation line to ensure it is securely attached to both the cuff and balloon.
7. Examine the aperture in mask. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. If the aperture bars are not intact, the epiglottis may obstruct the airway. Do not use if the aperture bar is damaged.

Pre-insertion Preparation:

Deflate completely using the LMA™ Cuff Deflator in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold back away from the aperture bars. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in blockage of aperture bar or aspiration of lubricant.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the LMA™ airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

Warning: Ensure all removable denture work is removed before inserting the device.

Insertion:

Note: Gloves must be worn

Standard Insertion Method:

1. **Anesthesia must be deep enough to permit insertion**

Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given.

2. Position the head and neck as for normal tracheal intubation. Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand (Fig.1).

3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube (Fig.1). Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.

4. Using the index finger, push the mask backwards still maintaining pressure against the palate (Fig.2).

5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion (Fig.3). Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. (Fig.3).

AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.

When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth (Fig.4).

6. Check that the black line on the tube faces the upper lip. Now immediately inflate the cuff without holding the tube. Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.

Warning: Never overinflate the cuff.

Maximum inflation volumes (ml)

Size 1	4ml	Size 3	20ml
Size 1½	7ml	Size 4	30ml
Size 2	10ml	Size 5	40ml
Size 2½	14ml	Size 6	50ml

7. Connect to gas supply, holding tube, to prevent displacement. Gently

inflate lungs to confirm correct placement. Insert roll of gauze as bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the device, it is important to remember to insert a bite block at the end of the procedure.

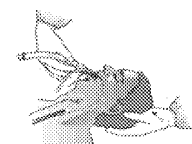


Figure 1

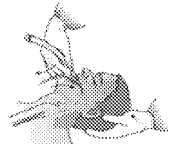


Figure 2

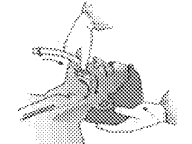


Figure 3

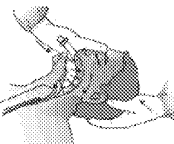


Figure 4

Thumb Insertion Method:

This technique is suitable for patients in whom access to the head from behind is difficult or impossible and during cardiopulmonary resuscitation. The LMA airway is held with the thumb in the position occupied by the index finger in the standard technique (Fig.5). The tip of the mask is pressed against the front teeth and the mask is pressed posteriorly along the palate with the thumb. As the thumb nears the mouth, the fingers are stretched forward over the patient's face (Fig.6). Advance the thumb to its fullest extent (Fig.7). The pushing action of the thumb against the hard palate also serves to press the head into extension. Neck flexion may be maintained with a head support. Before removing the thumb, push the tube into its final position using the other hand (Fig.8).

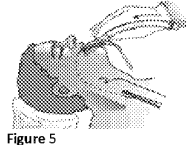


Figure 5

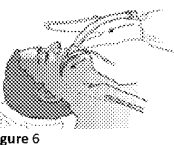


Figure 6

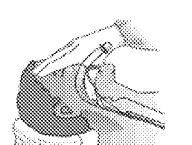


Figure 7

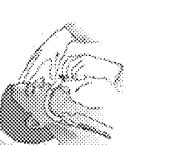


Figure 8

Maintaining the airway

1. Obstruction can occur if the LMA becomes dislodged, if the anatomy regains activity or if the balance between anesthesia depth and surgical stimulation intensity varies. Auscultation of both lungs and the anterolateral neck aids in understanding and correcting the situation. Various sounds (including stridor) heard during insufflation or inspiration at the level of the anterolateral neck are an indication of possible upper airway narrowing. Narrowing may be caused by: inadequate anesthesia depth, abnormal position at insertion, partial dislodgment of the mask, malposition of the head and neck or cervical

spine mobilization. In these circumstances, anesthesia depth

Suggested techniques for reinsertion of a dislodged or incorrectly inserted mask (potentially pushing down the epiglottis) include full deflation of the mask, a jaw thrust or use of laryngoscopes to lift the epiglottis anteriorly.

2. Malposition of mask tip into the glottis may mimic bronchospasm.

3. Avoid moving the device about in the pharynx when the patient is in a light plane of anesthesia.

4. Keep the bite-block in place until the device is removed.

5. Do not deflate the cuff until airway reflexes have fully returned.

6. Air may be withdrawn from the cuff during anesthesia to maintain a constant intra-cuff pressure (ideally about 60cm H₂O).

Removal

1. The LMA airway, together with the recommended bite-block, should be left in place until the return of consciousness. Oxygen should be administered using a "T" piece system and standard monitoring should be in place. Before attempting to remove or deflate the device, it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.

2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary to perform suction because the correctly used LMA airway protects the larynx from oral secretions. Patients will swallow secretions on removal. Suction equipment should however be available at all times.

3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

Fiber-optic intubation (only applicable for Classic Excel)

In anticipated difficult airway situations where and LMA airway will be used as a conduit for intubation the LMA Fastrach is recommended.

In an unanticipated difficult airway situation, intubation through the Classic Excel should be attempted only under direct visualization with a FOB. Refer to Table 1 for the maximum size ETT and FOB allowable for each size airway.

Table 1: Maximum ETT and FOB Sizes

Airway Size	ETT (mm)	FOB (mm)
3	7.0	5.0
4	7.0	5.0
5	7.5	5.5

Intubation

1. Load the ETT onto the FOB prior to insertion
 2. Orient the FOB so the tip flexes in the anteroposterior direction
 3. Pass the FOB without flexing it through the airway tube of the LMA Classic Excel
- Note: The epiglottis should be observed lying against the epiglottic elevating bar (EEB).
4. Once the vocal cords are visualized, pass the tip of the FOB into the trachea
 5. Thread the ETT downwards into the trachea over the FOB
 6. Inflate the ETT cuff and ventilate to check for correct position
 7. After confirmation of correct placement, fully deflate the cuff of the LMA Classic Excel and leave in place until ETT is extubated

Extubation

1. Without holding the tube, re-inflate the cuff of the LMA Classic Excel with an intracuff pressure no greater than 60 cm H₂O.
2. Deflate the cuff of the ETT
3. While holding the Classic Excel in place, slowly remove the ETT through the LMA Classic Excel to prevent removal or dislodgement of the airway.
4. Remove the LMA Classic Excel airway when protective reflexes have returned.

Gastric Drainage (only applicable for Classic Excel)

Gastric tubes compatible with the Classic Excel may be used to accomplish gastric drainage. It is recommended that the gastric tube be passed before inserting the Classic Excel. The insertion of a gastric tube does not guarantee that the stomach can be drained completely.

Cleaning (for LMA Classic™, LMA Classic Excel & LMA Flexible™ only): Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA airway use is Endozime® (Ruhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners or iodine-containing cleaners to clean or sterilize the LMA airway. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.

Caution: Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.

If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm flowing tap water, remove excess moisture, and allow it to dry. If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Clean the device using a small soft bristle brush (approximately 1/2 inch or 12.5 mm). Gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars. Thoroughly rinse the cuff and airway tube in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

Warning: Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.

Sterilization (for LMA Classic™, LMA Classic Excel & LMA Flexible™ only):

Immediately prior to steam autoclaving, deflate the cuff completely. Ensure that both the syringe used to deflate the cuff and the valve is dry.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon. To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port after deflation.

If a deflated mask immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the LMA airway, provided the maximum autoclave temperature does not exceed 137°C or 278.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

Caution: The integrity of the reusable LMA airway materials may be adversely affected by exceeding sterilization temperatures of 278.6°F or 137°C.

Autoclaves vary in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare personnel are responsible for adhering to the appropriate sterilization processes which have been specified. Failure to do so may invalidate the sterilization process of the healthcare facility. After autoclaving allow the device to cool to room temperature before use.

MRI Information



The LMA Classic, Classic Excel, Unique, Flexible and Flexible SU are MR Conditional. Non-clinical testing demonstrated that these products are MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape, or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence)

MRI-Related Heating

Under the scan conditions defined above, all LMA devices are expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 20-mm relative to the size and shape of the LMA Supreme, Size 5 which is also applicable to the LMA Classic, LMA Classic Excel and LMA Unique and approximately 50-mm relative to the size and shape of the LMA Flexible, Size 6.

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Symbol Definition:

	Manufacturer
	Authorized representative in the European Community
	Consult Instructions For Use on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	Serial Number
	Do not Re-use
	Do not reuse more than 40 times
	Non-sterile
	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)
	Sterilized by Ethylene Oxide
	Use By
	Do not use if package is damaged

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The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Manufacturer's Warranty:

The LMA Classic™ and LMA Flexible™ are reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

The LMA Unique™ and LMA Flexible™ Single Use are designed for single patient use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.



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Issue: PMS-2100-001 Rev B

Attachment # 5C

Instructions for Use revised to Supreme

English

Instructions for Use – LMA Supreme™

Caution: Federal (US) law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.

DEVICE DESCRIPTION

The LMA Supreme™ is a sterile, second generation, single use supraglottic airway management device.

The LMA Supreme™ provides access to and functional separation of the respiratory and digestive tracts. The anatomically shaped airway tube is elliptical in cross section and ends distally at the laryngeal mask. The inflatable cuff is designed to conform to the contours of the hypopharynx, with the bowl and the mask facing the laryngeal opening – the First Seal™.

The LMA Supreme™ also contains a drain tube which emerges as a separate port proximally and continues distally along the anterior surface of the cuff bowl, passing through the distal end of the cuff to communicate distally with the upper oesophageal sphincter – the Second Seal™.

The LMA Supreme™ has a new fixation system which prevents proximal displacement. If correctly used, this will enhance the seal of the distal end around the upper oesophageal sphincter – the Second Seal™ thereby isolating the respiratory tract from the digestive tract, so reducing the danger of accidental aspiration.

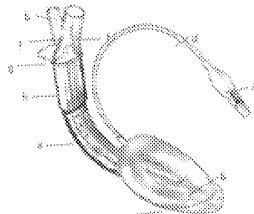


Figure 1: LMA Supreme™ components

LMA Supreme™ components (Figure 1):

- Anatomically-shaped airway tube
- A separate drain tube has been incorporated
- Inflatable cuff
- Cuff inflation line
- Pilot balloon
- A rigid molded proximal component which forms separate airway and drain tube ports
- Fixation tab
- Integral bite-block

INTENDED USE

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 (1) or Positive Pressure Ventilation (PPV) (2). LMA Supreme™ is also intended for use as a rescue device in emergency situations (3).

INDICATIONS FOR USE

The LMA Supreme™ is indicated for use as:

- An alternative to a face mask. (4, 5)
- An airway device in routine anesthesia procedures. (6, 7, 8)
- A rescue airway device in anticipated or unexpected difficult airway situations. (9, 10)
- A rescue airway device in CPR procedures. (11)
- 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 (12).

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. (5, 12)

Risk-Benefit Information

The benefits of establishing ventilation with the LMA Supreme™ must be weighed against the potential risk of aspiration in some situations including: symptomatic or untreated gastro-esophageal reflux, pregnancy over 14 weeks (12, 13, 14), multiple or massive injury (15), conditions associated with delayed gastric emptying, such as the use of opiate medication in patients with acute injury or peritoneal infectious or inflammatory processes.

When used in the profoundly unresponsive patient in need of resuscitation (2) or in a difficult airway patient on an emergency pathway (i.e. "cannot intubate, cannot ventilate") (2, 4) the LMA Supreme™ is the preferential airway "rescue" device to ensure oxygenation. The risk of regurgitation and aspiration is minimized as the LMA Supreme™ offers easy access to liquid gastric contents (17). However, the ultimate choice of the definite airway "rescue" device remains with the airway manager.

In patients with severe oropharyngeal trauma, the device should only

CONTRAINDICATIONS

The use of the LMA as a substitute for an endotracheal tube is not recommended in the following elective or difficult airway patients on a non-emergency pathway:

- Patients who have not fasted
- Patients whose fasting cannot be confirmed.
- Patients who are grossly or morbidly obese (5, 13, 5)
- Patients known to be using opiate medication prior to fasting.
- Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 30 cm H₂O (19)
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history
- Patients who have had radiotherapy to the neck involving the hypopharynx
- Patients with inadequate mouth opening to permit insertion
- Patients presenting for emergency surgery who are at risk of massive reflux, such as acute intestinal obstruction or ileus, or patients having been injured shortly after ingesting a substantial meal
- Patients requiring head or neck surgery where the surgeon cannot gain adequate access due to the presence of the device
- Patients who have ingested caustic substances
- The LMA Supreme should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist LMA Supreme insertion.

WARNINGS

- The LMA Supreme™ may not always protect from aspiration even when correctly fixed in place.
- Do not attempt to pass a gastric tube into the stomach via the drain tube in the presence of known or suspected esophageal pathology.
- There is a theoretical risk of causing edema or hematoma if suction is applied directly to the end of the drain tube.
- Refer to Appendix for MRI information prior to using LMA Supreme™ in MRI environment.
- The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily (typically less than 24 hours) with pregnant women, nursing mothers, babies and infants.
- To avoid trauma, excessive force should not be used at any time during insertion of the LMA Supreme™ or insertion of a gastric tube through the drain tube.
- The LMA Supreme™ is a single use device and it shall not be reused. The use of products intended for single patient use on more than one patient may result in degraded performance or loss of functionality and may also result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these products.
- Never over-inflate the cuff over 60cm H₂O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the LMA™ airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.
- Should the LMA Supreme be used in a fasted patient who is at risk of retained gastric contents, prophylactic measures should be employed by whenever possible.

CAUTIONS

- Do not immerse or soak the device in liquid prior to use.
- Only use with the recommended maneuvers described in the instructions for use.
- Do not use the LMA Supreme™ if the device is damaged or the unit packaging is damaged or opened.
- When applying lubricant avoid blockage of the airway aperture with the lubricant.
- If airway problems persist or ventilation is inadequate, the LMA Supreme™ should be removed and an airway established by some other means.
- Careful handling is essential. The LMA Supreme™ is made of medical-grade PVC which can be torn or perforated. Avoid contact with sharp or pointed objects at all times. Do not insert the device unless the cuff is fully deflated as described in the instructions for insertion.
- Gloves should be worn during preparation and insertion to minimize contamination of the airway.
- When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention.
- Only use syringe with standard luer taper tip for inflation/deflation of the cuff.
- Store device in a dark cool environment, avoiding direct sunlight or extremes of temperature.
- Used device shall be decontaminated first in accordance with local hospital procedures for handling bio-hazard products and subsequently

disposed of by incineration or landfill in accordance with all local and

12. Ensure all removable denture work is removed before inserting the device.

13. Ensure that pre-use checks are carried out on LMA™ airway prior to use, in order to establish whether they are safe for use.

ADVERSE EFFECTS

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks should be consulted for specific information.

SIZE SELECTION

For normal adults, use the size 4 device as a first choice. After inserting, fixing the device in place, and then inflating to the recommended pressure, there should be a minimum of one cm gap between the fixation tab and the patient's upper lip. If the tab is pressing on the lip or very near to it, this indicates the device is too small for the patient and the size 5 should be used instead to avoid the risk of (a) poor seal against the esophagus and (b) possible pressure trauma to the lip. If the fixation tab is more than 2.5 cm from the upper lip after fixation, it may be advisable to use the size 3 device. The decision to change to a smaller device will depend on the quality of airway, device stability and seal pressure achieved.



Figure 2: LMA Supreme™ sizing

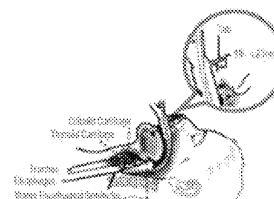


Figure 3: LMA Supreme™ sizing (method 2)

The sizing method described above requires that all three adult sizes of the LMA Supreme™ should be immediately available to hand before inducing anesthesia.

For adult patients who are either smaller or larger than average, it is often possible to obtain a good result using the size 4 device, provided the quantity of air used to inflate the cuff is always based on achieving 60 cm H₂O intra-cuff pressure. In smaller patients this pressure is achieved with a relatively small volume of air, while larger patients will require larger volumes. However, when in doubt, an approximate estimate of suitable sizing can be made by holding each device against the side of the patient's face in the position corresponding to that shown in figure 3.

PRE-USE PERFORMANCE TESTS

The following inspections and tests must be conducted before use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimize contamination of the LMA Supreme™ before insertion.

Warning: Do not use the device should it fail any one of the inspections or tests.

- Examine the surface of the LMA Supreme™ and drain tube for damage, including cuts, tears, scratches or kinks
- Examine the interior of the airway tube and drain tube to ensure they are free from blockages, kinking of the drain tube within the airway tube or loose particles. Any particles present in the tubes should be removed. Do not use the airway if the blockage or particle cannot be removed
- Deflate the cuff completely. Once deflated, check the cuff for spontaneous inflation. Do not use the airway if the cuff spontaneously inflates.

DEFLATING THE DEVICE PRIOR TO INSERTION

- After firmly connecting a syringe of at least 50ml to the inflation port, hold the syringe and the LMA Supreme™ exactly as shown in figure 4. Move the connected syringe away from the device until the inflation line is slightly stretched as shown. Compress the distal end of the device in between the index finger and thumb while withdrawing air until a vacuum has been obtained.
- While deflating, hold the device so that the distal end is curled slightly anteriorly as shown in Figure 4.
- Deflate the device until the tension in the syringe indicates a vacuum has been created in the mask. Keep the syringe under tension whilst rapidly disconnecting it from the inflation port. This will ensure the mask remains correctly deflated, as shown in Fig 5.



Figure 4: LMA Supreme™ deflation



Figure 5: After achieving wedge shaped cuff during deflation, disconnect the syringe from the inflation line

INSERTION

- Lubricate the posterior surface of the mask and airway tube just prior to insertion.
- Stand behind or beside patient's head.
- Place the head in the neutral or slight "sniffing" position (Sniffing = extension of head + flexion of neck).
- Hold the device exactly as shown in figure 6.
- Press the distal tip against the inner aspect of the upper teeth or gums.
- Slide inwards using a slightly diagonal approach (direct the tip away from the mid-line).
- Continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue.
- Resistance should be felt when the distal end of the device meets the upper esophageal sphincter. The device is now fully inserted.



Figure 6: Press the tip of the mask against the hard palate.



Figure 7: Maintaining pressure against the palate, continue to rotate the mask inwards



Figure 8: Swing the device in a circular motion following the curvature of the hard palate and soft palate



Figure 9: Continue until resistance is felt. The distal end of the mask should now be in contact with the upper esophageal sphincter. The device is now fully inserted.

FIXATION

- Secure the LMA Supreme™ to patient's face using adhesive tape as follows:
- Use a piece of adhesive tape 30-40cm long, holding it horizontally by both ends.
 - Press the adhesive tape transversely across the fixation tab, continuing to press downwards so that the ends of the tape adhere to each of the patient's cheeks and the device itself is gently pressed inwards by the tape.
 - Do not rotate the tape around the proximal end of the device.
 - Do not use a Guedel airway; the device has an integral bite block.

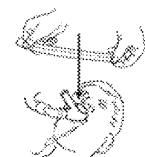


Figure 10a



Figure 10b

Figure 10: Fix the device in place using adhesive tape. Stretch the adhesive tape vertically downwards (See Figure 10a) and ensure that the middle of the tape is pressed vertically downwards over the tab as shown in Figure 10b.

INFLATION

Inflate the cuff with air until the intra-cuff pressure is reached. The recommended intra-cuff pressure is 60cm H₂O. If a cuff pressure manometer is at hand, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

Airway Size	Patient Weight	Max Size OG Tube	Recommended Maximum Inflation Volume	Optimum Intra-Cuff Pressure
1	< 5kg	6Fr	5ml	60cm H ₂ O
1.5	5-10kg	6Fr	8ml	
2	10-20kg	10Fr	12ml	
2.5	20-30kg	10Fr	20ml	
3	30-50kg	14Fr	30 ml	
4	50-70kg	14Fr	45 ml	60cm H ₂ O
5	70-100kg	14Fr	45 ml	

Table 1: LMA Supreme™ selection guide

CORRECT POSITION

Correct placement should produce a leak-free seal against the glottis with the mask tip at the upper esophageal sphincter. The integral bite block should lie between the teeth.

To facilitate diagnosis of correct mask placement, place a small bolus (1-2ml) of suitably viscous water soluble lubricant in the proximal end of the drain tube. In a properly placed mask, there should be a slight up-down meniscus movement of the lubricant following the application and release of gentle pressure in the suprasternal notch. This indicates that the distal end of the drain tube is correctly placed so that it seals around the upper esophageal sphincter (the 'suprasternal notch test'). A similar movement may also be seen when gentle manual positive pressure is applied to the airway through the device.

GASTRIC DRAINAGE

The drain tube facilitates channeling of fluids and gases emerging from the stomach. To facilitate gastric drainage, a gastric tube may be passed through the drain tube into the stomach at any time during the anesthetic procedure. Refer to Table 1 for maximum gastric tube sizes. The gastric tube should be well lubricated and passed slowly and carefully. Suction should not be performed until the gastric tube has reached the stomach. Suction should not be applied directly to the end of the drain tube, as this may cause the drain tube to collapse and might theoretically cause injury to the upper esophageal sphincter.

ANESTHESIA MAINTENANCE

The LMA Supreme™ is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anesthesia, provided anesthesia is adequate to match the level of surgical stimulus and the cuff is not over-inflated.

During PPV using the LMA Supreme™ tidal volumes should not exceed 8ml/kg and peak inspiratory pressures should be kept below the maximum airway seal pressure.

If leaks occur during PPV, this may be due to light anesthesia causing a degree of glottic closure, severe reduction in lung compliance related to the procedure or patient factors or displacement or migration of the cuff by head turning or traction in an inadequately fixed mask.

RECOVERY

Removal should always be carried out by trained personnel. If the device is not removed in the operating room, its low invasivity makes it a good device to maintain the airway during recovery in the Post Anesthetic Care Unit (PACU) provided staff are appropriately trained and equipped. Because recovery involves increase in pharyngeal tone, it makes sense to reduce the volume of air in the cuff before sending the patient to the PACU; however, the cuff must never be fully deflated at this point.

Fully deflate the cuff and simultaneously remove the device ONLY when the patient can open the mouth on command. If the cuff is FULLY deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm.

Patient monitoring should continue throughout the recovery stage. Where appropriate, oxygen may be continuously administered through the anesthetic circuit or via a T-piece attached to the proximal end of the airway device.

MRI Information



The LMA Supreme is MR Conditional. Non-clinical testing demonstrated that the LMA Supreme is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence)

MRI-Related Heating

Under the conditions defined above, the LMA Supreme is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 20-mm relative to the size and shape of the LMA Supreme, Size 5.

18. SYMBOLS DEFINITION

	Manufacturer
	Authorized representative in the European Community
	Consult Instructions For Use on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	Do not Re-use
	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)
	Sterilized by Ethylene Oxide
	Use By
	Do not use if package is damaged

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The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Consult the instructions on indications, contraindications, warnings and precautions, or information on which LMA™ airways are best suited for different clinical applications.

Manufacturer's Warranty:

The LMA Supreme™ is designed for a single patient use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.



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Issue: TBD

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Attachment # 5D

Instructions for Use revised for ProSeal

English

Instructions for Use – LMA ProSeal™

Caution: Federal (US) law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.

WARNING: LMA ProSeal™ is supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

Device Description:

The LMA ProSeal™ is a second generation, reusable supraglottic airway management device.

The LMA ProSeal™ provides access to and functional separation of the respiratory and digestive tracts. The anatomically shaped airway tube is elliptical in cross section and ends distally at the laryngeal mask. The inflatable cuff is designed to conform to the contours of the hypopharynx, with the bowl and the mask facing the laryngeal opening – the First Seal™

The LMA ProSeal™ also contains a drain tube which emerges as a separate port proximally and continues distally along the anterior surface of the cuff bowl, passing through the distal end of the cuff to communicate distally with the upper oesophageal sphincter – the Second Seal™

Intended Use:

The LMA ProSeal™ is intended for use in achieving and maintaining control of the airway during routine anesthetic procedures on fasted patients using either spontaneous (1) or Positive Pressure Ventilation (PPV) (2). LMA ProSeal™ is also intended for use as a rescue device in emergency situations (3).

Indication for Use:

The LMA ProSeal™ is indicated for use as:

1. An alternative to a face mask. (4, 5)
2. An airway device in routine anesthesia procedures. (6, 7, 8)
3. A rescue airway device in anticipated or unexpected difficult airway situations. (9, 10)
4. A rescue airway device in CPR procedures. (11)

The LMA ProSeal™ may be used to establish an immediate clear airway during resuscitation of the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation. (12)

Risk-Benefit Information:

The benefits of establishing ventilation with the LMA ProSeal™ must be weighed against the potential risk of aspiration in some situations including: symptomatic or untreated gastro-esophageal reflux, pregnancy over 14 weeks (5, 9, 13), multiple or massive injury (14), conditions associated with delayed gastric emptying, such as the use of opiate medication in patients with acute injury or peritoneal infectious or inflammatory processes.

Contraindications:

The use of the LMA as a substitute for an endotracheal tube is not recommended in the following elective or difficult airway patients on a non-emergency pathway:

- Patients who have not fasted
- Patients whose fasting cannot be confirmed
- Patients who are grossly or morbidly obese
- Patients more than 14 weeks pregnant (2)
- Resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist device insertion
- Patients with any condition associated with delayed gastric emptying (15)
- Patients known to be using opiate medication prior to fasting
- Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 30 cm H₂O
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history
- Patients who have had radiotherapy to the neck involving the hypopharynx
- Patients with inadequate mouth opening to permit insertion
- Patients presenting for emergency surgery who are at risk of massive reflux, such as acute intestinal obstruction or ileus, or patients having been injured shortly after ingesting a substantial meal
- Patients requiring head or neck surgery where the surgeon cannot gain adequate access due to the presence of the device
- Patients who have ingested caustic substances

Warnings:

1. Do not attempt to pass a gastric tube into the stomach via the drain tube in the presence of known or suspected esophageal pathology.
2. There is a theoretical risk of causing edema or hematoma if suction is applied directly to the end of the drain tube.
3. Refer to Page 2 for information prior to using LMA ProSeal™ in MRI environment.
4. The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.

5. To avoid trauma, excessive force should not be used at any time during insertion of the LMA ProSeal™. Do not use caustic substances through the drain tube.
6. Never over-inflate the cuff over 60cm H₂O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
7. A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the LMA™ airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

Precautions:

1. Do not immerse or soak the device in liquid prior to use.
2. Only use with the recommended maneuvers described in the instructions for use.
3. Do not use the LMA ProSeal™ if the device is damaged or the unit packaging is damaged or opened.
4. When applying lubricant avoid blockage of the airway aperture with the lubricant.
5. If airway problems persist or ventilation is inadequate, the LMA ProSeal™ should be removed and an airway established by some other means.
6. Careful handling is essential. Avoid contact with sharp or pointed objects at all times. Do not insert the device unless the cuff is fully deflated as described in the instructions for insertion.
7. Gloves should be worn during preparation and insertion to minimize contamination of the airway.
8. Laryngeal spasm may occur if the patient becomes too lightly anesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, do not remove the LMA™ airway, but treat the cause. Only remove the device when airway protective reflexes are fully competent.
9. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention.
10. Only use syringe with standard luer taper tip for inflation/deflation of the cuff.
11. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperature.
12. Ensure all removable denture work is removed before inserting the device.
13. It is important that pre-use checks are carried out on LMA™ airway prior to use, in order to establish whether they are safe for use. Failure of any one test indicates the device should not be used.

Adverse Effects

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks should be consulted for specific information.

Preparation for Use:

Choose the correct size of LMA ProSeal™

Patient Weight/Size

- | | |
|---------------------------|--------------------------------|
| 1: up to 5kg neonatal | 3: 30kg - 50kg Pediatric/Adult |
| 1½: 5kg - 10kg Pediatric | 4: 50kg - 70kg Adult |
| 2: 10kg - 20kg Pediatric | 5: 70kg - 100kg Adult |
| 2½: 20kg - 30kg Pediatric | |

Caution: Clinical judgment should be used in the selection of the appropriate device size for an individual patient.

Pre-Use Checks

It is most important that pre-use checks are carried out on LMA ProSeal™ prior to use, in order to establish whether they are safe for use.

Warning: Failure of any one test indicates the device should not be used.

These tests should be carried out as follows:

1. **Examine interior of the airway tube, mask bowl and drain tube** to ensure they are free from blockage, loose particles, damage, cuts, tears or scratches.
2. **Examine the airway connector.** It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
3. **Examine rear cuff** for wrinkles or folds suggesting herniation.
4. **Deflate the cuff fully.** Reinflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 1	6ml	Size 3	30ml
Size 1½	10ml	Size 4	45ml
Size 2	15ml	Size 5	60ml
Size 2½	21ml		

Examine the cuff for leaks, non-symmetry, herniations and uneven bulging. A herniating mask may cause obstruction during use. While the device remains 50% over-inflated, examine the inflation pilot balloon and interior of the drain tube. The balloon shape should be elliptical, not spherical. The drain tube should not be collapsed or perforated.

Warning: Use of an LMA ProSeal™ with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the device from being inflated or allow for escape of anesthetic gases.

5. **Discoloration.** Discoloration affects visibility of fluid in the airway tube.

Pre-insertion Preparation:

Prior to deflating LMA ProSeal™ and during clinical use, ensure the red plug is closed.

Inflate completely by hand manually or using the LMA™ Cuff Deflator or LMA ProSeal™ Cuff Deflator in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. Ensure back of mask is straight without any curvature of the distal end; distal end should be maximally flattened. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in aspiration of lubricant.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the LMA™ airway components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

Warning: Ensure all removable denture work is removed before inserting the device.

Insertion:

Note: gloves must be worn

Index Finger Insertion Technique:

1. Anesthesia must be deep enough to permit insertion.

Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given.

2. Position the head and neck as for normal tracheal intubation.

Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand.

3. When inserting the mask, hold it like a pen with the index finger pushed into the introducer strap (Fig. 1). Press the tip of the cuff upwards against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx (Fig. 2).

4. Slide the mask inward, extending the index finger still maintaining pressure against the hard palate.

5. Press the finger towards the other hand which exerts counter pressure (Fig. 3).

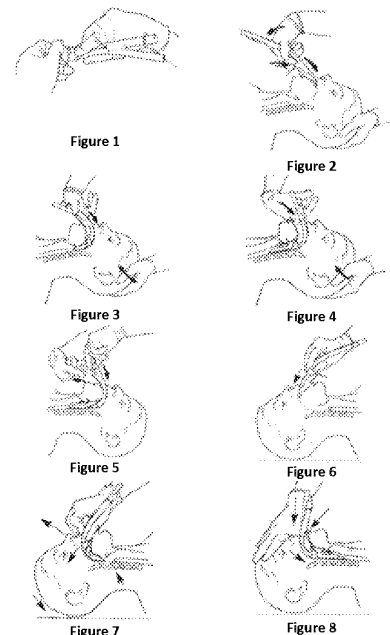
6. Advance the device into the hypopharynx by fully extending the index finger and flexing the wrist until a definite resistance is felt (Fig. 4).

7. Gently press the outer end of the airway tube while removing the index finger (Fig. 5). After insertion, the tubes should emerge from the mouth directed caudally.

8. **Without holding to the tubes,** inflate the cuff with just enough air to achieve an intracuff pressure of 60cm H₂O.

Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.

Warning: NEVER OVERINFLATE THE CUFF.



Maximum inflation volumes (ml)

Size 1	4ml	Size 3	20ml
Size 1½	7ml	Size 4	30ml
Size 2	10ml	Size 5	40ml
Size 2½	14ml		

Keep a clearly marked syringe for inflation and deflation of the cuff.

9. Connect to gas supply, holding tube, to prevent displacement.

Gently inflate lungs to confirm correct placement.

10. All sizes of LMA ProSeal™ have a built-in bite-block except size 1. Tape the device in place and fix it with the outer end extending over the chin in the mid-line. Ensure the tip of the mask is pressed securely against the upper esophageal sphincter. For size 1, take extra care during fixation of the airway to ensure the cuff does not rotate and become displaced.

Thumb Insertion Technique:

This technique is suitable for patients in whom access to the head from behind is difficult or impossible and during cardiopulmonary

resuscitation. The device is held with the thumb inserted into the strap. The tip of the mask is pressed against the palate (Fig. 6). As the thumb nears the mouth, the fingers are stretched forward over the patient's face (Fig. 7). Advance the thumb to its fullest extent (Fig. 8). The pushing action of the thumb against the hard palate also serves to press the head into extension. Neck flexion may be maintained with a head support. Before removing the thumb, push the tube into its final position using the other hand (Fig. 9).

LMA ProSeal™ Introducer Insertion Technique:

This technique is recommended for LMA ProSeal™ size 1 to 2½.

1. Place tip of the introducer into the strap at the rear of the LMA ProSeal™ cuff (Fig. 10). Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the introducer (Fig. 11).
2. Press the tip of the cuff upward against the hard palate and flatten the cuff against it (Fig. 12).
3. With the bowl of the mask facing the tongue, slide the cuff inward against the hard palate. Ensure the tip of the cuff is not folded (Fig. 13).
4. Keeping the introducer blade close to the chin, rotate the device inward in one smooth circular movement (Fig. 14).
5. During insertion, follow the curve of the rigid insertion device. The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask. Do not use the handle as a lever to force the mouth open.
6. Advance into the hypopharynx until a definite resistance is felt (Fig. 15).
7. Before removing the introducer, the non-dominant hand is brought from behind the patient's head to stabilize the airway tube, preventing LMA ProSeal™ from being pulled out of place (Fig. 16).

Caution: The introducer should be removed prior to inflation and fixation of the LMA ProSeal™.



Figure 9



Figure 10



Figure 11



Figure 12

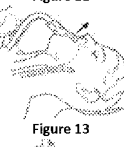


Figure 13

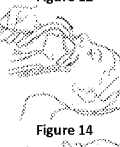


Figure 14



Figure 15



Figure 16

Use of Drain Tube

Warning: Do not attempt to pass a gastric tube through the LMA ProSeal™ drain tube if there is gas leaking through the drain tube or in the presence of known or suspected esophageal pathology or damage.

If it is clinically indicated to pass a gastric tube into the stomach, suction should not be performed until the gastric tube has reached the stomach.

Warning: Suction should not be applied directly to the end of drain tube, as this may cause the drain tube to collapse and cause possible injury to the upper esophageal sphincter

The primary function of the drain tube is to provide a separate conduit from and to the alimentary tract. It may direct gases or liquids from the patient and may also serve as a guide for blind insertion of an oro-gastric tube at any time during the anesthetic.

The oro-gastric tube should be well-lubricated and passed slowly and carefully. Ensure the tube is at or above room temperature. Do not use oro-gastric tubes which have been stiffened by refrigeration.

Upon insertion, some resistance may be detected as the tip of the catheter is pressed gently against the upper sphincter. Do not use excessive force. If a tube of appropriate size fails to pass, the mask may be kinked or malpositioned. In these cases, the mask should be removed and reinserted. Clinical judgment should be used in deciding when the oro-gastric tube should be removed.

Removal

1. LMA ProSeal™ should be left in place until the return of consciousness. Oxygen should be administered using a "T" piece system and standard monitoring should be in place. Before attempting to remove or deflate the device, it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.

2. Look for the onset of swallowing which indicates reflexes are almost restored. Mouthpiece is removed and patient is instructed to breathe the correctly used LMA™ airway protects the larynx from oral secretions. Patients will swallow secretions on removal. **Suction equipment should however be available at all times.**
3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

Cleaning:

Note: The LMA™ airway accessories (i.e. LMA ProSeal™ Introducer and LMA ProSeal™ Cuff Deflator) should be cleaned and sterilized in the same manner as LMA ProSeal™.

Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Endozime® (Ruhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners or iodine-containing cleaners to clean or sterilize the LMA ProSeal™. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.

Caution: Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.

Caution: Close the LMA ProSeal™ red plug during cleaning to prevent exposure of the valve to any cleaning solution.

If moisture is noticed in the red plug, open the plug and tap against a towel to remove excess moisture.

When cleaning the LMA ProSeal™, ensure the areas behind the LMA ProSeal™ Introducer strap and under the internal drain tube are clean. Clean the tubes using a small soft bristle brush (approximately 1/4 inch or 6mm in diameter for adult size device). Gently insert the brush through the proximal (outer) end of the drain tube, taking care not to damage the drain tube.

Thoroughly rinse the cuff, airway tube and drain tube in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

Warning: Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.

Sterilization:

For LMA ProSeal™ without red plug

Immediately prior to steam autoclaving, deflate the cuff completely. Ensure that both the syringe used to deflate the cuff and the valve is dry.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.

To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port after deflation.

If a deflated mask immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the LMA ProSeal™, provided the maximum autoclave temperature does not exceed 137°C or 278.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

Caution: The integrity of the reusable LMA™ airway materials may be adversely affected by exceeding sterilization temperatures of 137°C or 278.6°F.

Autoclaves vary in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare personnel are responsible for adhering to the appropriate sterilization processes which have been specified. Failure to do so may invalidate the sterilization process of the healthcare facility.

After autoclaving allow the device to cool to room temperature before use.

For LMA ProSeal™ with red plug

It is not necessary to deflate the cuff prior to steam autoclaving. It is therefore normal for LMA ProSeal™ to be inflated upon removal from autoclave, provide the manual vent is in the open position.

Caution: Ensure LMA ProSeal™ manual vent is open during sterilization to prevent herniation of the cuff.

MRI Information



MR Conditional

Non-clinical testing demonstrated that the LMA ProSeal is MR Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence)

MRI-Related Heating

Under the scan conditions defined above, the LMA ProSeal is expected to produce a maximum temperature rise of 2.2°C after 15 minutes of continuous scanning.

Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 50-mm relative to the size and shape of the LMA ProSeal 5.

Symbol Definition:

	Manufacturer
	Authorized representative in the European Community
	Consult Instructions For Use on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	Serial Number
	Do not reuse more than 40 times
	Non-sterile
	Do not use if package is damaged



The Laryngeal Mask Company Limited
Le Rocher, Victoria, Mahé, Seychelles
www.LMACO.com



Issue: TBD

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The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Manufacturer's Warranty:

The LMA ProSeal™ is reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

Warranty is applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@fda.hhs.gov or 301-796-8118

6

510(k) Summary

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Indications for Sue statements for all devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Classic™, Classic™ Excel, Unique™ and Flexible™

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Fastrach™

Indications for Use (Describe)

The LMA Fastrach™ is indicated for use in achieving and maintaining control of the airway during anticipated or unanticipated difficult airways and emergency anesthetic procedures using either spontaneous or Positive Pressure Ventilation (PPV). LMA Fastrach™ is also intended for use as a rescue device in emergency situations.

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.

- 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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

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Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Fastrach™ ETT

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

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Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Supreme

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA ProSeal

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Section 19 – Electromagnetic Compatibility and Electrical Safety,
Environmental and Mechanical Testing

<u>19</u>	<u>Electromagnetic Compatibility and Electrical Safety, Environmental and Mechanical Testing</u>	<u>Page</u>
<u>19.1</u>	<u>Electromagnetic Compatibility and Electrical Safety</u>	<u>2</u>
<u>19.2</u>	<u>Environmental and Mechanical Testing</u>	<u>2</u>

19.1 Electromagnetic Compatibility and Electrical Safety

The LMA™ airway devices are not electrically operated and therefore EMC and Electrical safety testing is not applicable.

19.2 Environmental and Mechanical Testing

There have been no changes in the components, materials, manufacturing or sterilization method, thus there is no need to redo environmental or mechanical testing on the finished device or its components.

I understand thank you.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Friday, May 30, 2014 1:16 PM

To: Mendoza, Mario

Subject: RE: K130304S4 memo

Ok, but it will be about 1 hour before I can get to it. On a conference call

(b)(4)

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

Web - www.promedic.cc<http://www.promedic.cc/>

Twitter - https://twitter.com/ProMedicInc

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]

Sent: Friday, May 30, 2014 1:14 PM

To: Paul Dryden

Subject: K130304S4 memo

(b)(4)

Thanks and sorry about all of this back and forth,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney, Todd D

Sent: Friday, May 30, 2014 11:50 AM

To: Mendoza, Mario

Subject: RE: K130304S4 memo

(b)(5)

From: Mendoza, Mario

Sent: Friday, May 30, 2014 10:54 AM

To: Courtney, Todd D

Subject: K130304S4 memo

(b)(5)

Mario R. Mendoza, M.D., MS

Medical Officer

CDRH/ODE/DAGRID/ANDB

WO66, Room 2563

Office: (240) 402-5121

Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

From: Courtney, Todd D

Sent: Friday, May 30, 2014 10:35 AM

To: Mendoza, Mario

Subject: RE: K130304S4

(b)(5)

See comment in memo.

From: Mendoza, Mario

Sent: Friday, May 30, 2014 9:52 AM

To: Courtney, Todd D

Subject: RE: K130304S4

(b)(5)

(b)(5)

Thanks,

M

Mario R. Mendoza, M.D., MS

Medical Officer

CDRH/ODE/DAGRID/ANDB

WO66, Room 2563

Office: (240) 402-5121

Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

From: Courtney, Todd D

Sent: Thursday, May 29, 2014 9:22 PM

To: Mendoza, Mario

Subject: RE: K130304S4 (b)(5)

(b)(5)

Thanks,

Todd

From: Mendoza, Mario

Sent: Thursday, May 29, 2014 4:14 PM

To: Courtney, Todd D

Subject: RE: K130304S4 (b)(5)

Thanks Todd,

(b)(5)

M

Mario R. Mendoza, M.D., MS

Medical Officer

CDRH/ODE/DAGRID/ANDB

WO66, Room 2563

Office: (240) 402-5121

Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

From: Courtney, Todd D

Sent: Thursday, May 29, 2014 10:30 AM

To: Mendoza, Mario

Subject: RE: K130304S4 (b)(5)

Hi Mario,

(b)(5)

Thanks,

Todd

From: Mendoza, Mario

Sent: Wednesday, May 28, 2014 2:29 PM

To: Courtney, Todd D

Subject: K130304S4 (b)(5)

Hi Todd,

(b)(5)

Thanks for your review,

Mario

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Wednesday, January 29, 2014 5:20 PM
To: Mendoza, Mario
Subject: RE: K130304/S003

Dr, Mendoza

Thank you for this, I will review with Teleflex.

I take note on the extension to respond of COB 2/3.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) -- +239-498-2155
M -- (b)(6)
F -- +239-236-0354
E -- drydenp@promedic.cc
Web -- www.promedic.cc

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Wednesday, January 29, 2014 5:17 PM
To: Paul Dryden
Subject: K130304/S003

Dear Mr. Dryden:

(b)(4)

(b)(4)

Please let me know if you have any questions.
Sincerely,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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<u>04</u>	<u>Coversheet and Checklist</u>	<u>Page</u>
<u>04.1</u>	<u>CDRH Premarket Review Submission Coversheet</u>	<u>2</u>
<u>04.2</u>	<u>Refuse to Accept Checklist – Traditional Submission</u>	<u>9</u>

04.1 CDRH Premarket Review Submission Coversheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission 5-Feb-13		User Fee Payment ID Number (b)(4)	
		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information
		Meeting ☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other (<i>specify</i>):	
		Other Submission ☐ 513(g) ☐ Other (<i>describe submission</i>):	
Have you used or cited Standards in your submission? ☒ Yes ☐ No			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company name The Laryngeal Mask Company Limited		FDA establishment number 9681900	
Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>) +011 65 64946889	
Street Address PO Box 221, Le Rocher		FAX Number (<i>including area code</i>) +011 65 64946989	
City Victoria	State / Province Mahe	ZIP/Postal Code	Country Seychelles
Contact Name Sharon Wong			
Contact Title Regulatory Affairs Manager		Contact E-mail Address <u>sharon.wond@lmaco.com.sg</u>	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Teleflex Medical, Inc		Phone Number (<i>including area code</i>) 858-622-5621	
Division Name (<i>if applicable</i>)		FAX Number (<i>including area code</i>) 919-433-4996	
Street Address 2917 Weck Drive, PO Box 12600		FAX Number (<i>including area code</i>) 919-433-4996	
City Research Triangle Park	State / Province NC	ZIP/Postal Code 27709	Country USA
Contact Name Kate Rizzo			
Contact Title Senior Manager, Regulatory Affairs and Quality Assurance		Contact E-mail Address <u>krizzo@lmana.com</u>	

Form FDA 3514 (12/10)		Page 1 of
SECTION D1		REASON FOR APPLICATION - PMA, PDP, OR HDE
☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (<i>specify below</i>)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager
☐ Process change: ☐ Manufacturing ☐ Sterilization ☐ Packaging ☐ Other (<i>specify below</i>)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (<i>specify below</i>)	☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Response to FDA correspondence:		☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address
☐ Other Reason (<i>specify</i>):		
SECTION D2		REASON FOR APPLICATION - IDE
☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Other Reason (<i>specify</i>):		
SECTION D3		REASON FOR SUBMISSION - 510(k)
☐ New Device	☒ Additional or Expanded Indications	☐ Change in Technology
☐ Other Reason (<i>specify</i>):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS								
Product codes of devices to which substantial equivalence is claimed							Summary of, or statement concerning, safety and effectiveness information ☒ 510 (k) summary attached ☐ 510 (k) statement	
1	CAE	2	CAE	3	CAE	4		BTR
5	BTR	6		7		8		
Information on devices to which substantial equivalence is claimed (if known)								
	510(k) Number		Trade or Proprietary or Model Name			Manufacturer		
1	K904834	1	LMA Classic™		1	LMA		
2	(b)(4)	2	LMA ProSeal™		2	LMA		
3	(b)(4)	3	LMA Unique™ LMA Classic Excel™ LMA Flexible™ LMA Flexible™ Single Use LMA Supreme™ LMA Fastrach™ Single Use		3	LMA		
4	K051993	4	LMA Fastrach™ ETT Single Use		4	LMA		
5	K991580	5	LMA Fastrach™ ETT (reusable)		5	LMA		
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS								
Common or usual name or classification (b)(6) airway, oropharyngeal, anesthesiology (CAE) / tracheal tube (BTR)								
	Trade or Proprietary or Model Name for This Device				Model Number			
1	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™				1			
FDA document numbers of all prior related submissions (regardless of outcome)								
1	K904834	2	(b)(4)	3	K991580	4	K051993	
Data Included in Submission ☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials								
Product Code CAE / BTR		C.F.R. Section applicable) 868.5110 / 868.5730			Device Class ☒ Class I ☒ Class II ☐ Class III ☐ Unclassified			
Classification Panel Anesthesiology								

Indications (from labeling)

The indications for the LMA Unique™, LMA Classic™, LMA Classic Excel™, LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™ are unchanged from their original indications. We are adding:

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

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	Contact E-mail Address
☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete		FDA Establishment Registration Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City			State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. F2052-06	Standards Organization ASTM	Standards Title Standard Test Method for Magnetically Induced Displacement Force in MR field	Version 06e1	Date 2006
2	Standards No. F2503-08	Standards Organization ASTM	Standards Title Standard Practice for Marking Devices in MR Environment	Version 08	Date 2008
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Dept. of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Dr., Room 400
Rockville, MD 20850

04.2 Refuse to Accept Checklist – Traditional Submission

For convenience we have included and completed the Refuse To Accept Checklist (Elements of a Complete Submission - RTA Items per 21 CFR 807.87 unless otherwise indicated)

Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____

Date Received: _____

Lead Reviewer Name: _____ Branch: _____

Division: _____ Office: _____

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments C AE – airway, oropharyngeal, anesthesiology; BTR – tracheal tube		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."	X	
Comments: CDRH / ODE / Anesthesiology		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following:	N/A	

a) Is the device or combination product the same (e.g., design, formulation as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i> If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
Comments:		
4. Is this device type eligible for 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments: Class 1 – CFR 868.5110 – C AE – airway, oropharyngeal, anesthesiology Class 2 – CFR 868.5730 – BTR – tracheal tube		
5. Is there a pending PMA for the same device with the same indications for use? If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 4 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation

	Yes	No
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	X	
Comments: See Sec 2 Table of Contents and Sec 5 Cover Letter		

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
A.	Administrative			
	1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X		☐
	Comments:			
	2. Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter:	X		☐
	a. Device trade name or proprietary name	X		☐
	b. Device common name	X		☐
	c. Device class and panel Classification regulation or Statement that the device has not been classified with rationale for that conclusion.	X		☐
	Comments: Sec 4 Form FDA 3514 CDRH Premarket Review submission Cover Sheet			
	3. Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	X		☐
	Comments: Section 4			
	4. Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.</i>	X		☐
	a. Summary contains all elements per 21 CFR 807.92 <i>See also <u>510(k) Summary Checklist</u></i>	X	☐	☐
	b. Statement contains all elements per 21 CFR 807.93	☐	X	☐
	Comments: Section 7			
	5. Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended <u>format</u></i>	X		☐

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	Comments: Section 8			
6.	Submission contains Class III Summary and Certification <i>See recommended <u>content</u></i> <i>Form should be signed by a responsible person of the firm, not a consultant.</i> <i>CDRH is not currently able to accept a digital signature.</i> <i>"N/A" only if submission is not a Class III 510(k).</i>	☐	X	☐
	Comments: Sec 9 Class I and Class II device			
7.	Does submission contain clinical data? <i>Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.</i>			X
	a. Submission includes Financial Certification (3454) /Disclosure (3455) Statement		X	☐
	b. Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (<u>FDA Form 3674</u>) (42 U.S.C. 282(j)(5)(B))	X	☐	☐
	Comments: Sec 10 and Sec 22			
8.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (<u>FDA Form 3654</u>) or includes detailed information about how and the extent to which the standard has been followed. <i>There should be a completed form for each referenced national or international standard.</i> <i>Select "N/A" only if submission does not reference any standards</i>	X		☐
	Comments: Sec 11 Form 3654			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

			Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
9.		The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.	X		☐
	a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	X		☐
Comments: Sec 4 Form FDA 3514, Sec 5, Sec 14					
B.	Device Description				
10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	☐	X	☐
10.	b.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches. Select "N/A" if there is no device-specific guidance document, Select "No" if the submission does not include a rational for any omitted information or any alternative approach as outlined above.</i>	☐	X	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	N/A	No
	Comments:			
11.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.		X	☐
b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		X	☐
c.	A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one model.</i>	X		☐
	Comments: See Section 13 Device Description			
12.	Submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. <i>In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i> <i>Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>		X	☐
	Comments: See Section 11 Device Description			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		X	
a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	X	☐
b.	Submission includes a description (as detailed above) of each component or accessory.	☐	X	☐
c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.</i>	☐	X	☐
Comments: Section 13				
C.	Substantial Equivalence Discussion			
14.	Submitter has identified a predicate(s) device	X		☐
a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		☐
b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	X		☐
Comments: Section 14				
15.	Submission includes a comparison of the following for the predicate(s) and subject device			
a.	Indications for use	X		☐
b.	Technology, including features, materials, and principles of operation	X		☐
Comments: Section 14 Substantial Equivalence				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) <i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.</i>	X	☐	☐
Comments: See Section 14 Substantial Equivalence				
D.	Proposed Labeling (see also 21 CFR part 801) <i>If in vitro diagnostic (IVD) device, criteria may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section below.</i>		☐	
17.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use	X	☐	☐
a.	Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	X		☐
b.	Submission includes directions for use that - Include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D)	X		☐
Comments: Section 15 Labeling				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				
18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also <u>Alternative to Certain Prescription Device Labeling Requirements</u>] <i>Select "N/A" if not indicated for prescription use.</i>	X	☐	☐
Comments: Section 15 Labeling				
19.	General labeling provisions			
a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		☐
b.	Labeling includes device common or usual name (21 CFR 801.61)	☐	X	☐
Comments: Section 15 Labeling				
20. a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	☐	X	☐
b.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no device-specific guidance or regulation.</i>	☐	X	☐
c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document.</i>	☐	X	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	Comments:			
	21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>	☐	X	☐
E.	Sterilization <i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A" if not an in vitro diagnostic device.</i>		X	
	Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> ☐ provided sterile ☐ non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist. If information regarding the sterility status of the device is not provided, select "No."</i>			☐
	Comments:			
	22. Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	☐	☐	☐
	b. Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☐	☐
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☐
	Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				
23.	If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.</i>		☐	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
	b. A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	☐		☐
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	☐	☐	☐
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	☐		☐
	e. Sterility Assurance Level (SAL) stated	☐		☐
Comments:				
24.	If the device, and/or accessory, and/or a component is end user sterilized: <i>Select "N/A" if no part of the device, accessories or components are end user sterilized, otherwise complete a-d below.</i>		X	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		1.1 Any "No" answer will result in a "Refuse to Accept" decision.	Yes	N/A	No
		1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation is not required.</i>	☐		☐
	c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
	d.	Submission includes sterilization instructions for end user.	☐		☐
Comments:					
25.	a.	If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.	☐	X	☐
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	☐	X	☐
	c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness	☐	X	☐
Comments: Section 18					
F.	Shelf Life				
26	Proposed shelf life/expiry date stated <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>		☐	X	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select "N/A" if the device is not provided sterile.</i>	☐	X	☐
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X		☐
	Comments: No change in Shelf-life			
G.	Biocompatibility			
	Submission states that there: <i>(one of the below must be checked)</i> X are are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i>			
	Comments: See Section 17			
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☐	X	☐
	Comments:			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐	X	☐
	Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐	X	☐
H.	Software			
Submission states that the device: <i>(one of the below must be checked)</i> ___ does X does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i>				X
Comments:				
32.	Submission includes a statement of software level of concern and rationale for the software level of concern		X	☐
Comments: Section 16 Software				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	N/A	No
33.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u> , or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.		X	☐
	Comments: Section 18 Software			
I.	EMC and Electrical Safety			
	Submission states that the device: <i>(one of the below must be checked)</i> ☐ does X does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i>			X
	Comments: Section 19			
34.	Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	☐		☐
	Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
35.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	☐		☐
	Comments:			
J.	Performance Data – General <i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i>	X	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				
36.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.)	X	☐	☐
Comments: Section 20				
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	☐	X	☐
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	☐	X	☐
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	☐	X	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No
	1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
Comments:				
38.	If literature is referenced in the submission, submission includes:		X	
	a. Legible reprints or a summary of each article	☐	X	☐
	b. Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	X	☐
Comments:				
39.	For each completed nonclinical (i.e., animal) study conducted, Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations which t "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations which are assessed in Section G of the checklist.		X	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐		☐
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	☐		☐
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))			
Submission indicates that device: (one of the below must be checked) ☐ is X is not an in vitro diagnostic device (IVD). <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>				
Comments:				
40.	Submission includes the following studies as appropriate for the device type, including associated protocol description, study results and line data:			

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(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

1.1 Any "No" answer will result in a "Refuse to Accept" decision. 1.2 Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			Yes	N/A	No
	a	Precision/reproducibility	☐	☐	☐
	b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐
	c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
	d.	Analytical specificity	☐	☐	☐
Comments:					
41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device specific requirement.	☐	☐	☐
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	☐	☐	☐
	c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	☐	☐	☐

Decision: Accept ____ Refuse to Accept ____

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature_____ **Date:**_____

Supervisory Signature_____ **Date:**_____

February 22, 2013</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

<p>We have completed the administrative acceptance review of your premarket notification (510(k)) submission K130304. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold. </p>

<p>Please submit two copies of your response, referencing the 510(k) number K130304, addressing the elements identified as missing or inconsistent in the attached checklist to:</p>

<p style="padding-left:50">U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - W066-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002</p>

<p>FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.</p>

<p>Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission. </p>

<p>Should you have questions about this email, you may contact Mario Mendoza, the lead reviewer assigned to your 510(k) submission.</p>



Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Teleflex Incorporated
2917 Weck Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

August 19, 2013

Subject: K130304 – Response to Refuse to Accept for LMA Airways for
MR Conditional use

Dear Dr. Mendoza:

This is response to the Refuse to Accept e-mail of 2/22/13 for K130304.

eCopy STATEMENT

In accordance with Section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission.
It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency as presented in the “Comments” section of the Refuse To Accept Checklist.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission 19-Aug-13		User Fee Payment ID Number (b)(4)	
		FDA Submission Document Number (if known)	
SECTION A		TYPE OF SUBMISSION	
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information
		Meeting ☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other (<i>specify</i>):	
		Other Submission ☐ 513(g) ☐ Other (<i>describe submission</i>):	
Have you used or cited Standards in your submission? ☒ Yes ☐ No			
SECTION B		SUBMITTER, APPLICANT OR SPONSOR	
Company name The Laryngeal Mask Company Limited		FDA establishment number 9681900	
Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>) +011 65 64946889	
Street Address PO Box 221, Le Rocher		FAX Number (<i>including area code</i>) +011 65 64946989	
City Victoria	State / Province Mahe	ZIP/Postal Code	Country Seychelles
Contact Name Sharon Wong			
Contact Title Regulatory Affairs Manager		Contact E-mail Address sharon.wond@lmaco.com.sg	
SECTION C		APPLICATION CORRESPONDENT (e.g., consultant, if different from above)	
Company / Institution Name Teleflex Medical, Inc		Phone Number (<i>including area code</i>) 239-498-2155	
Division Name (<i>if applicable</i>)		FAX Number (<i>including area code</i>) 239-236-0354	
Street Address 2917 Weck Drive, PO Box 12600		FAX Number (<i>including area code</i>) 239-236-0354	
City Research Triangle Park	State / Province NC	ZIP/Postal Code 27709	Country USA
Contact Name Paul Dryden			
Contact Title Consultant		Contact E-mail Address drydenp@promedic.cc	

Form FDA 3514 (12/10) 5SECTION D1		Page 1 of
REASON FOR APPLICATION - PMA, PDP, OR HDE		
☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (<i>specify below</i>)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager
☐ Process change: ☐ Manufacturing ☐ Sterilization ☐ Packaging ☐ Other (<i>specify below</i>)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (<i>specify below</i>)	☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Response to FDA correspondence:		☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address
☐ Other Reason (<i>specify</i>):		

SECTION D2		REASON FOR APPLICATION - IDE
☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final		
☐ Other Reason (<i>specify</i>):		

SECTION D3		REASON FOR SUBMISSION - 510(k)
☐ New Device	☒ Additional or Expanded Indications	☐ Change in Technology
☐ Other Reason (<i>specify</i>):		

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information ☒ 510 (k) summary attached ☐ 510 (k) statement					
1	CAE	2	CAE			3	CAE	4	BTR
5	BTR	6				7		8	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K904834	1	LMA Classic™	1	LMA
2	Class 1 exempt	2	LMA ProSeal™	2	LMA
3	Class 1 exempt	3	LMA Unique™ LMA Classic Excel™ LMA Flexible™ LMA Flexible™ Single Use LMA Supreme™ LMA Fastrach™ LMA Fastrach™ Single Use	3	LMA
4	K051993	4	LMA Fastrach™ ETT Single Use	4	LMA
5	K991580	5	LMA Fastrach™ ETT (reusable)	5	LMA

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

airway, oropharyngeal, anesthesiology (CAE) / tracheal tube (BTR)

	Trade or Proprietary or Model Name for This Device		Model Number
1	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™	1	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
No prior submissions					

Data Included in Submission		
☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials		
Product Code CAE / BTR	C.F.R. Section <i>applicable</i>) 868.5110 / 868.5730	Device Class ☒ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel Anesthesiology		
Indications <i>(from labeling)</i> The indications for the LMA Unique™, LMA Classic™, LMA Classic Excel™, LMA Flexible™, LMA Flexible™ Single Use, LMA ProSeal™, LMA Fastrach™ Single Use, and LMA Supreme™ are unchanged from their original indications. The LMA Fastrach™ ETT and LMA Fastrach™ ETT 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. We are adding to the labeling: That they can be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title	Contact E-mail Address	
☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. F2052-06	Standards Organization ASTM	Standards Title Standard Test Method for Magnetically Induced Displacement Force in MR field	Version 06e1	Date 2006
2	Standards No. F2503-08	Standards Organization ASTM	Standards Title Standard Practice for Marking Devices in MR Environment	Version 08	Date 2008
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Dept. of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Dr., Room 400 Rockville, MD 20850 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control					

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Attachment # 1 – Instructions for Use.

We have included the Instructions for Use which cover the following LMA products.

Label for -

- LMA Classic™ (reusable)
- LMA Classic Excel™ (reusable)
- LMA Flexible™ (reusable)
- LMA Flexible™ Single Use
- LMA Unique™ Single Use

Label for –

- LMA ProSeal™ (reusable)

Label for -

- LMA Fastrach™ ETT (reusable)
- LMA Fastrach™ Single Use
- LMA Fastrach™ ETT Single Use

Label for -

- LMA Supreme™ Single Use

Label for -

- LMA Classic™ (reusable)
- LMA Classic Excel™ (reusable)
- LMA Flexible™ (reusable)
- LMA Flexible™ Single Use
- LMA Unique™ Single Use



The Laryngeal Mask Company Limited

English

Instructions for Use

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-15-2024

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Label for –

- LMA ProSeal™ (reusable)



The Laryngeal Mask Company Limited

English

Instructions for Use (b)(4)

Records processed under FOIA Request 2024-6295; Released by CDRH on 11/14/2024

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Label for -

- LMA Fastrach™ ETT (reusable)
- LMA Fastrach™ Single Use
- LMA Fastrach™ ETT Single Use



The Laryngeal Mask Company Limited

English

Instructions for Use

Records processed under FOIA Request 2024-6295; Released by CDRH on 11/14/2024

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Label for -

- LMA Supreme™ Single Use



The Laryngeal Mask Company Limited

English

Instructions for Use

(b)(4)

Records processed under FOIA Request 2024-6295; Released by CDRH on 11/14/2024

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Memo

To: Mario Mendoza

From: Wolfgang Kainz

CC: H. Bassen, V. Krauthamer, T. Woods

Date: 12 MAR 2013

Re: K130304 - Laryngeal Mask Company LMA Airways

Digitally signed by Wolfgang N. Kainz
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, cn=Wolfgang N. Kainz,
0.9.2342.19200300.100.1.1=1300202342
Date: 2013.03.12 14:31:06 -07'00'

(b)(5)

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Dear Mr. Dryden:

(b)(4)

Given the clarification that was needed based on our telephone conversation, please provide your response to the above deficiencies (as well as those posed in our January 27, 2014 email) via email to me by close of business February 3, 2014.

Please let me know if you have any questions.
Sincerely,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CONSULTING MEMO

Date: January 24, 2014

To: Mario Mendoza, M.D., M.S.
CDRH/ODE/DAGRID/ANDB

From: Daniel Krainak, PhD
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

A handwritten signature in black ink, appearing to read 'DKrainak', is written over a circular official stamp.

Daniel Krainak
2014.01.24 11:41:48 -05'00'

Subject: K130304/S003
Laryngeal Mask Airways (LMAs)
Laryngeal Mask Company

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S003

Date: January 29, 2014

To: The Record

From: Mario Mendoza, MD

Office: ODE

Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

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SIGNATURES

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mario Mendoza -S 2014.02.11 16:59:04 -05'00'
Branch Chief Sign-Off (Optional)	
Division Sign-Off (Optional)	

Mario R. Mendoza, M.D., MS
FDA Commissioner's Fellow
CDRH/ODE/DAGRID/ANDB
WO66, Room 2523
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Mario Mendoza [mailto:mario.mendoza@fda.hhs.gov]
Sent: Friday, February 22, 2013 4:50 PM
To: KRIZZO@LMANA.COM
Cc: Mendoza, Mario
Subject: K130304 was Refused

February 22, 2013

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K130304. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response, referencing the 510(k) number K130304, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Mario Mendoza, the lead reviewer assigned to your 510(k) submission.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130304/S003

Date: January 29, 2014

To: The Record

From: Mario Mendoza, MD

Office: ODE

Division: DAGRID/ANDB

510(k) Holder: Teleflex Medical, Inc. (The Laryngeal Mask Company Limited, a subsidiary of Teleflex Medical, Inc.)

Device Name: LMA Airways

Contact: Paul Dryden c/o Teleflex Medical, Inc.

Phone: 239-498-2155

Fax: 239-236-0354

Email: drydenp@promedic.cc

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Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Monday, February 10, 2014 6:00 PM
To: Mendoza, Mario
Subject: RE: K130304/S003

Thank you for confirming.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
F - + 239-236-0354
E -- drydenp@promedic.cc
Web -- www.promedic.cc

"The information contained in this message may be privileged, confidential, and protected from disclosure. If you are not the intended recipient, or an employee, or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting from your computer. Additionally, even if the intended recipient, any dissemination, distribution, or copying of this communication may still be prohibited if not previously understood and/or agreed upon by sender."

From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Monday, February 10, 2014 5:52 PM
To: Paul Dryden
Subject: RE: K130304/S003

Mr. Dryden,
The file has been placed on a second telephone hold and you have up to 180 days to respond, from 2/11/14 since it is after close of business today.
Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Monday, February 10, 2014 5:49 PM
To: Mendoza, Mario
Subject: RE: K130304/S003

Dr. Mendoza

I wanted to acknowledge receipt of this e-mail.

It appears that we have been given a second hold and up to 180 days to respond, from 2/10/14, please confirm

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
F - +239-236-0354
E - drydenp@promedic.cc
Web - www.promedic.cc

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Thank you for the meeting minutes Mr. Dryden,
Some minor edits included and file attached.
Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
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Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Mendoza, Mario
Sent: Wednesday, June 04, 2014 10:13 AM
To: 'Paul Dryden'; Courtney, Todd D
Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)
Subject: RE: K130304 (b)(4)

Mr. Dryden,
We are in discussion with 510k staff and will respond to you shortly.

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [<mailto:drydenp@promedic.cc>]
Sent: Tuesday, June 03, 2014 5:48 PM
To: Courtney, Todd D
Cc: Mendoza, Mario; Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)
Subject: K130304 (b)(4)

Mr. Courtney and Dr. Mendoza:

(b)(4)

Should you have any questions, please feel free to call me.

I left a voicemail this evening for Todd alerting him of the issue.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M (b)(6)
F - +239-236-0354
E - drydenp@promedic.cc
Web - www.promedic.cc
Twitter - <https://twitter.com/ProMedicInc>

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Dear Mr. Dryden:

(b)(4)

Given the clarification that was needed based on our telephone conversation, please provide your response to the above deficiencies (as well as those posed in our January 27, 2014 email) via email to me by close of business February 3, 2014.

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Monday, February 10, 2014 6:00 PM
To: Mendoza, Mario
Subject: RE: K130304/S003

Thank you for confirming.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
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Web - www.promedic.cc<http://www.promedic.cc/>

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Monday, February 10, 2014 5:52 PM
To: Paul Dryden
Subject: RE: K130304/S003

Mr. Dryden,

The file has been placed on a second telephone hold and you have up to 180 days to respond, from 2/11/14 since it is after close of business today.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Monday, February 10, 2014 5:49 PM

To: Mendoza, Mario

Subject: RE: K130304/S003

Dr. Mendoza

I wanted to acknowledge receipt of this e-mail.

It appears that we have been given a second hold and up to 180 days to respond, from 2/10/14, please confirm

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

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E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

Web - www.promedic.cc<http://www.promedic.cc/>

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immediately by replying to the message and deleting from your computer. Additionally, even if the intended recipient, any dissemination, distribution, or copying of this communication may still be prohibited if not previously understood and/or agreed upon by sender."

Mr. Dryden,

The file has been placed on a second telephone hold and you have up to 180 days to respond, from 2/11/14 since it is after close of business today.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Monday, February 10, 2014 5:49 PM

To: Mendoza, Mario

Subject: RE: K130304/S003

Dr. Mendoza

I wanted to acknowledge receipt of this e-mail.

It appears that we have been given a second hold and up to 180 days to respond, from 2/10/14, please confirm

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

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E - drydenp@promedic.cc

Web - www.promedic.cc

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K130304/A1
Teleflex®

2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

03-Apr-13

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
APR 08 2013
Received

Re: K130304 – LMA MR – Change in Submission Correspondent

Dear Mr. Mario Mendoza:

We wish to inform you that we need to change the original submission correspondent for K130304.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

NEW OFFICIAL CORRESPONDENT

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

Tel – 239-498-2155
Fax – 239-236-0354
E – drydenp@promedic.cc

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Liz Paul
Director, Regulatory Affairs/Quality Engineering
Anesthesia/Respiratory

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

<u>16</u>	<u>Sterilization, Shelf Life, and Cleaning Information</u>	<u>Page</u>
<u>16.1</u>	<u>Sterilization</u>	<u>2</u>

16.1 Sterilization

This submission is for the addition of MR Conditional environment of use.

There are no changes in the sterilization or cleaning methods for the proposed devices.

Teleflex®

Teleflex Incorporated

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P.O. Box 12000
Research Triangle Park,
NC 27709

USA

Phone: 658-622-5621

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www.teleflex.com

05-Feb-13

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **TRADITIONAL** 510(k) Notification for LMA Airways for MR Conditional use

Dear Sir or Madam:

The Laryngeal Mask Company Limited (a subsidiary of Teleflex Medical) is submitting this **Traditional** 510(k) Notification for the LMA™ family of airways to expand the indications for use to include use in Magnetic Resonance imaging locations under a MR conditional labeling.

We have prepared this **Traditional** submission based upon available *Guidance* documents for 510(k) submissions.

BUNDLED SUBMISSION

As permitted we are bundling the Class 1 exempt product classification CAE (oropharyngeal airway) with Class 2 product classification – BTR (tracheal tubes) as this submission is for expanding the indications for use to include MR conditional settings. The test data and thus the review can be performed by the same reviewer.

We have prepared separate Indications for Use statements, Section 6 for each device.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

TYPE OF SUBMISSION

Traditional

PAYMENT IDENTIFICATION NUMBER

The MDUFMA PIN is (b)(4)

TRADE NAMES

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™

DEVICE TYPE

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 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 tracheal tube, LMA Fastrach™ ETT tube, both reusable and single use, is considered a Class 2 device, for which we are seeking the same change in indications for use as MR conditional.

SUBMITTER

The Laryngeal Mask Company Limited
PO Box 221, Le Rocher
Victoria, Mahe, Seychelles

OFFICIAL CORRESPONDENT

Kate Rizzo
c/o Teleflex Medical, Inc.
2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

Tel: 858-622-5621
Fax: 919-433-4989
E-mail: krizzo@lmana.com

CONFIDENTIALITY

We request as outlined under 21 CFR 807.95 that FDA treat this premarket notification and our intent to market as confidential commercial information under the conditions and requirements of CFR 807.95.

CLASS / CLASSIFICATION / PRODUCT CODE

Class 1 – CFR 868.5110 – CAE – airway, oropharyngeal, anesthesiology
Class 2 – CFR 868.5730 – BTR – tracheal tube

PANEL

Anesthesiology



PREVIOUS FDA DOCUMENTS

LMA has submitted the LMA Classic™ under K904834 and the (b)(4)
(b)(4) Subsequently the product classification was confirmed as (b)(4)
The LMA Fastrach™ ET tube, reusable and single use, were cleared under K991580 and K051993, respectively.

BASIS FOR THE SUBMISSION

To seek MR Conditional environment of use.

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		No
Does the device contain components derived from a tissue or other biologic source?		No
Is the device provided sterile?	Yes	
Is the device intended for single use?	Yes	No
Is the device a reprocessed single use device?		No
If yes, does this device type require reprocessed validation data?		No
Does the device contain a drug?		No
Does the device contain a biologic?		No
Does the device use software?		No
Does the submission include clinical information?		No
Is the device implanted?		No

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Senior Manager, Regulatory Affairs and Quality Assurance

3 Medical Device User Fee Cover Sheet

The following User Fee has been paid by ProMedic as the consultant assisting with for this submission, however as indicated in **Section 4 – CDRH Cover Sheet** and **Section 5 – Cover Letter**, the sponsor and official correspondent for the submission are as follows:

SUBMITTER

The Laryngeal Mask Company Limited
PO Box 221, Le Rocher
Victoria, Mahe, Seychelles

OFFICIAL CORRESPONDENT

Kate Rizzo
c/o Teleflex Medical, Inc.
2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

Tel: 858-622-5621
Fax: 919-433-4996
E-mail: krizzo@lmana.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdulma/cover-sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) PROMEDIC INC 24301 Woodsage Drive Bonita Springs FL 34134-2858 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4839		2. CONTACT NAME Paul Dryden 2.1 E-MAIL ADDRESS drydenp@promedic.cc 2.2 TELEPHONE NUMBER (include Area code) 239-4982155 2.3 FACSIMILE (FAX) NUMBER (include Area code) 239-2360354	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdulma) <u>Select an application type:</u> ☒ Premarket notification (510(k)); except for third party ☐ 513(g) Request for information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ 30-Day Notice <u>Select a center:</u> ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) ☐ NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdulma for additional information.)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). ☐ YES ☒ NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) 28-Jan-2013			

Form FDA 3601 (01-2007)



Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Teleflex Incorporated
2917 Weck Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

September 4, 2013

Subject: K130304 – Response to Refuse to Accept for LMA Airways for
MR Conditional use

Dear Dr. Mendoza:

This is response to the Refuse to Accept e-mail of 9/4/13 for K130304.

eCopy STATEMENT

In accordance with Section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission.
It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency as presented in the “Comments” section of the Refuse To Accept Checklist.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

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(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment # 2 – 510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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Research Triangle Park, NC 27709

03-Apr-13

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K130304 – LMA MR – Change in Submission Correspondent

Dear Mr. Mario Mendoza:

We wish to inform you that we need to change the original submission correspondent for K130304.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

NEW OFFICIAL CORRESPONDENT

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

Tel – 239-498-2155
Fax – 239-236-0354
E – drydenp@promedic.cc

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Liz Paul
Director, Regulatory Affairs/Quality Engineering
Anesthesia/Respiratory

18 Software

The LMA™ airway devices do not incorporate any software.

K130304/S003
Teleflex

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

JAN 15 2014

Received

Teleflex Incorporated
2017 Weck Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

January 14, 2014

Subject: K130304 – Response for LMA Airways for MR Conditional use

Dear Mr. Parvinian:

This is our response to the deficiency e-mail dated November 1, 2013 for K130304.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

cll

Hi Mr. Dryden,

I will do my best to accommodate the times for today, I will need to have the MR consultant involved in the conversation. Once I can confirm with the MR consultant, then I will confirm with you for today or for later in the week.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [<mailto:drydenp@promedic.cc>]

Sent: Tuesday, January 28, 2014 8:36 AM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: K130304/S003 request for teleconference

Dr. Mendoza:

We would like to have a conference call today, 1/28, any time between 1 - 2:30 or 4-5:00 EST, to discuss some of the questions and requests made 1/27 for K130304, the Teleflex LMA submission.

Since we are under a short timeline, we would appreciate your accommodating this request.

Participating would be

Liz Paul -- Teleflex Director RA/QE Anesthesia/Respiratory

Justin Lovelace -- Regulatory Affairs Specialist

Please confirm a time and we will set call a call in number.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T - +239-498-2155

M - [REDACTED] (b)(6)

F - +239-236-0354

E -- drydenp@promedic.cc

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Mr. Dryden,

The file has been placed on a second telephone hold and you have up to 180 days to respond, from 2/11/14 since it is after close of business today.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Monday, February 10, 2014 5:49 PM

To: Mendoza, Mario

Subject: RE: K130304/S003

Dr. Mendoza

I wanted to acknowledge receipt of this e-mail.

It appears that we have been given a second hold and up to 180 days to respond, from 2/10/14, please confirm

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

Web - www.promedic.cc<http://www.promedic.cc/>

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Dear Mr. Dryden:

(b)(4)

Given the clarification that was needed based on our telephone conversation, please provide your response to the above deficiencies (as well as those posed in our January 27, 2014 email) via email to me by close of business February 3, 2014.

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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Dear Mr. Dryden:

(b)(4)

Given the clarification that was needed based on our telephone conversation, please provide your response to the above deficiencies (as well as those posed in our January 27, 2014 email) via email to me by close of business February 3, 2014.

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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K130304/5001

Teleflex

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

AUG 20 2013

Received

Teleflex Incorporated
2517 West Gate
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

August 19, 2013

Subject: K130304 – Response to Refuse to Accept for LMA Airways for
MR Conditional use

Dear Dr. Mendoza:

This is response to the Refuse to Accept e-mail of 2/22/13 for K130304.

eCopy STATEMENT

In accordance with Section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission.
It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency as presented in the "Comments" section of the Refuse To Accept Checklist.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

31

From: Smith, Alysia * [Alysia.Smith@fda.hhs.gov]
Sent: 5/27/2014 3:14:15 PM
To: DRYDENP@PROMEDIC.CC
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304.S004 ACK LETTER
Attachments: K130304.S004 ACK LETTER.pdf



Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 27, 2014

THE LARYNGEAL MASK CO.,LTD.
C/O TELEFLEX MEDICAL, INC.
2917 WECK DR
PO BOX 12600
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
ATTN: PAUL DRYDEN

510k Number: K130304

Product: LMA FAMILY OF AIRWAYS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

FDA CDRH DMC

FEB 07 2013

Received

Teleflex®

Teleflex Incorporated

2917 Weick Drive
P.O. Box 12000
Research Triangle Park,
NC 27709
USA
Phone: 858-822-5021
Fax: 919-433-4989

www.teleflex.com

05-Feb-13

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **TRADITIONAL** 510(k) Notification for LMA Airways for MR Conditional use

Dear Sir or Madam:

The Laryngeal Mask Company Limited (a subsidiary of Teleflex Medical) is submitting this **Traditional** 510(k) Notification for the LMA™ family of airways to expand the indications for use to include use in Magnetic Resonance imaging locations under a MR conditional labeling.

We have prepared this **Traditional** submission based upon available *Guidance* documents for 510(k) submissions.

BUNDLED SUBMISSION

As permitted we are bundling the Class 1 exempt product classification CAE (oropharyngeal airway) with Class 2 product classification – BTR (tracheal tubes) as this submission is for expanding the indications for use to include MR conditional settings. The test data and thus the review can be performed by the same reviewer.

We have prepared separate Indications for Use statements, Section 6 for each device.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

TYPE OF SUBMISSION

Traditional

PAYMENT IDENTIFICATION NUMBER

The MDUFMA PIN is (b)(4)

TRADE NAMES

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™

DEVICE TYPE

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 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 tracheal tube, LMA Fastrach™ ETT tube, both reusable and single use, is considered a Class 2 device, for which we are seeking the same change in indications for use as MR conditional.

SUBMITTER

The Laryngeal Mask Company Limited
PO Box 221, Le Rocher
Victoria, Mahe, Seychelles

OFFICIAL CORRESPONDENT

Kate Rizzo
c/o Teleflex Medical, Inc.
2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

Tel: 858-622-5621
Fax: 919-433-4989
E-mail: krizzo@lmana.com

CONFIDENTIALITY

We request as outlined under 21 CFR 807.95 that FDA treat this premarket notification and our intent to market as confidential commercial information under the conditions and requirements of CFR 807.95.

CLASS / CLASSIFICATION / PRODUCT CODE

Class 1 – CFR 868.5110 – CAE – airway, oropharyngeal, anesthesiology
Class 2 – CFR 868.5730 – BTR – tracheal tube

PANEL

Anesthesiology



PREVIOUS FDA DOCUMENTS

LMA has submitted the LMA Classic™ under K904834 and the LMA ProSeal™ under K001425. Subsequently the product classification was confirmed as Class 1 exempt.

The LMA Fastrach™ ET tube, reusable and single use, were cleared under K991580 and K051993, respectively.

BASIS FOR THE SUBMISSION

To seek MR Conditional environment of use.

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		No
Does the device contain components derived from a tissue or other biologic source?		No
Is the device provided sterile?	Yes	
Is the device intended for single use?	Yes	No
Is the device a reprocessed single use device?		No
If yes, does this device type require reprocessed validation data?		No
Does the device contain a drug?		No
Does the device contain a biologic?		No
Does the device use software?		No
Does the submission include clinical information?		No
Is the device implanted?		No

Please do not hesitate to contact me should you have any questions or require any additional information.

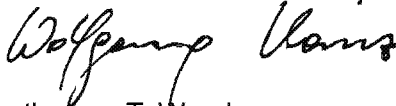
Sincerely,

(b)(6)

Senior Manager/Regulatory Affairs and Quality Assurance

Memo

To: Mario Mendoza

From: Wolfgang Kainz 

CC: H. Bassen, V. Krauthamer, T. Woods

Date: 20 JAN 2014

Re: K130304-S003 - Laryngeal Mask Company LMA Airways

Digitally signed by Wolfgang N. Kainz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300202342,
cn=Wolfgang N. Kainz -S
Date: 2014.01.20 11:08:36 -08'00'

(b)(5)

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Wednesday, January 29, 2014 12:23 PM
To: Mendoza, Mario
Subject: RE: K130304 telecon meeting minutes.01 28 14.doc

Thank you and changes / edits noted.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
F - + 239-236-0354
E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>
Web - www.promedic.cc<http://www.promedic.cc/>

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Wednesday, January 29, 2014 12:10 PM
To: Paul Dryden
Subject: K130304 telecon meeting minutes.01 28 14.doc

Thank you for the meeting minutes Mr. Dryden,
Some minor edits included and file attached.

Mario Mendoza, M.D.
Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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September 4, 2013</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

<p>We have completed the administrative acceptance review of your premarket notification (510(k)) submission K130304/S001. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold. </p>

<p>Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K130304/S001, addressing the elements identified as missing or inconsistent in the attached checklist to:</p>

<p style="padding-left:50">U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - W066-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002</p>

<p>FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.</p>

<p>Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission. </p>

<p>Should you have questions about this email, you may contact Mario Mendoza, the lead reviewer assigned to your 510(k) submission.</p>

<p>For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.</p>

<p>****This is a system generated email notification****</p>

I understand the issue, so I will try my best to get the MR consultant (who is also critical) to be available today.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Tuesday, January 28, 2014 11:07 AM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: RE: K130304/S003 request for teleconference

Thank you but according to your email we must respond by 1/31, so there is not much time. Also Ms. Paul is traveling and may not be available and it is critical that she is part of the call.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T - +239-498-2155

M - [REDACTED] (b)(6)

F - +239-236-0354

E -- drydenp@promedic.cc

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]

Sent: Tuesday, January 28, 2014 11:03 AM

To: Paul Dryden

Subject: RE: K130304/S003 request for teleconference

Hi Mr. Dryden,

I will do my best to accommodate the times for today, I will need to have the MR consultant involved in the conversation. Once I can confirm with the MR consultant, then I will confirm with you for today or for later in the week.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov

Phone: 240.402.5121

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From: Collins, Virginia * [Virginia.Collins@fda.hhs.gov]
Sent: 6/3/2014 6:03:15 PM
To: drydenp@promedic.cc
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304 SE letter
Attachments: K130304.pdf



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.

Page 2 – Mr. Dryden

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" (21 CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

Indications for Use Statement

Page 1 of 1

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney-S
2014.05.29 20:59:02 -04'00'

Indications for Use Statement

Page 1 of 1

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)

Todd D. Courtney-S
2014.05.29 20:59:24
-04'00'

Page 06.3



Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Teleflex Incorporated
2917 Weck Drive
P.O. Box 12600
Research Triangle Park
NC 27709
USA
www.teleflex.com

January 14, 2014

Subject: K130304 – Response for LMA Airways for MR Conditional use

Dear Mr. Parvinian:

This is our response to the deficiency e-mail dated November 1, 2013 for K130304.

eCopy STATEMENT

In accordance with section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission. It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency.

Please do not hesitate to contact me should you have any questions or require any additional information.
Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

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Attachment # 1 – Indications for Use statement (Form 3881)

IFU LMA Classic
IFU LMA Fastrach
IFU LMA ProSeal
IFU LMA Supreme

IFU LMA Classic

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

(b)(4)

IFU LMA Fastrach

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

(b)(4)

IFU LMA ProSeal

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

(b)(4)

IFU LMA Supreme

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

(b)(4)

Attachment # 2 – 510(k) Summary

510(k) Summary

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Attachment # 3 – Instructions for Use – revised

**LMA Classic, LMA Unique, LMA Excel and LMA Flexible
LMA Fastrach
LMA ProSeal
LMA Supreme**

LMA Classic, LMA Unique, LMA Excel and LMA Flexible



The Laryngeal Mask Company Limited

English

**Instructions for Use – LMA Classic™, LMA
Classic Excel™, LMA Flexible™, LMA Flexible™
Single Use & LMA Unique™**

Caution: Federal (U.S) law restricts this device to sale by or on the
order of a physician

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

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LMA Fastrach



The Laryngeal Mask Company Limited

English

Instructions for Use – LMA Fastrach™, LMA
Fastrach™ Single Use, LMA Fastrach™ ETT &
LMA Fastrach™ ETT Single Use

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LMA ProSeal

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LMA Supreme



The Laryngeal Mask Company Limited

English

Instructions for Use – LMA Supreme™

Records processed under FOIA Request 2024-6295 Released by CDRH on 11/14/2024

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Attachment # 4 – MR Test Reports revised

SHELLOCK LMA Supreme report revised

SHELLOCK LMA Flexible report revised

SHELLOCK LMA Fastrach report revised

SHELLOCK LMA ProSeal report revised

SHELLOCK LMA Supreme report revised

(b)(4)

REPORT
Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Supreme, Size 5

Project Conducted by:

(b)(4)

06/07/10 – Revised 12/17/13

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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SHELLOCK LMA Flexible report revised

(b)(4)

REPORT
Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Flexible, Size 6

Project Conducted by:

(b)(4)

06/08/10 REVISED 12/17/13

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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SHELLOCK LMA Fastrach report revised

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SHELLOCK LMA ProSeal report revised

(b)(4)

REPORT
**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA ProSeal, Size 5**

Project Conducted by:

(b)(4)

06/09/10 REVISED 12/17/13

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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Mr. Dryden,

We are in receipt of your response.

Thank you,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Monday, February 03, 2014 1:55 PM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: RE: K130304/S003 Response

Dr. Mendoza:

Please find attached our responses to your interactive review questions of 1/27 and 1/29/14 for K130304.

Should you have any questions please advise.

Please confirm receipt.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T (office) - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

Web - www.promedic.cc<http://www.promedic.cc/>

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]

Sent: Wednesday, January 29, 2014 5:17 PM

To: Paul Dryden

Subject: K130304/S003

Dear Mr. Dryden:

(b)(4)

(b)(4)

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Wednesday, January 29, 2014 12:23 PM
To: Mendoza, Mario
Subject: RE: K130304 telecon meeting minutes.01 28 14.doc

Thank you and changes / edits noted.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T {office} - +239-498-2155
M - (b)(6)
F - + 239-236-0354
E -- drydenp@promedic.cc
Web -- www.promedic.cc

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From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Wednesday, January 29, 2014 12:10 PM
To: Paul Dryden
Subject: K130304 telecon meeting minutes.01 28 14.doc

Thank you for the meeting minutes Mr. Dryden,
Some minor edits included and file attached.

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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09 Premarket Notification Class III Certification and Summary
(As Required by 21 CFR 807.94)

(To be submitted when claiming equivalence to a Class III device)

The proposed devices, LMA™ airways, are not claiming equivalence to a Class III device, therefore the summary and certification is not required.

Mr. Dryden,
We are in receipt of your response.
Thank you,
Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [<mailto:drydenp@promedic.cc>]
Sent: Monday, February 03, 2014 1:55 PM
To: Mendoza, Mario
Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)
Subject: RE: K130304/S003 Response

Dr. Mendoza:

Please find attached our responses to your interactive review questions of 1/27 and 1/29/14 for K130304.

Should you have any questions please advise.

Please confirm receipt.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T (office) - +239-498-2155
M - (b)(6)
F - + 239-236-0354
E -- drydenp@promedic.cc
Web -- www.promedic.cc

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From: Mendoza, Mario [<mailto:Mario.Mendoza@fda.hhs.gov>]
Sent: Wednesday, January 29, 2014 5:17 PM
To: Paul Dryden
Subject: K130304/S003

Dear Mr. Dryden:

(b)(4)

(b)(4)

Please let me know if you have any questions.
Sincerely,

Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.
This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K130304

Date Received by DCC: September 3, 2013

Lead Reviewer: Mario Mendoza

Branch: ANDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed

Yes

No

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

×

Comments?

2. Is the application with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."

×

Comments?

3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question is no, mark "No." If there was no RFD, skip this question.

Comments?

4) Is this device type eligible for a 510(k) submission?

If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."

×

Comments?

5) Is there a pending PMA for the same device with the same indications for use?

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.

X

Comments?

6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm>

X

Comments?

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)
Revised Process and Order Form Request for Pre-Submission Review on 11/14/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	×			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	×			
a) Device trade name or proprietary name	×			
b) Device common name	×			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	×			
4) Submission contains 510(k) Summary or 510(k) Statement	×			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	×			
b) Statement contains all elements per 21 CFR 807.93			×	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format.	×			
6) Submission contains Class III Summary and Certification. See recommended content.	×			
7) Submission contains clinical data			×	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	×			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	×			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	×			

B. Device Description

10)	
-----	--

Elements of a Complete Submission (RTA Items)

Records processed under FOIA Request # 2022-0001 Released by DOR on 04/10/2024

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	×			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×			
c) A list and description of each device for which clearance is requested.	×			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	×			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	×			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	×			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	×			

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	×			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	×			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	×			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	×			
b) Technology, including features, materials, and principles of operation	×			

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	-----	----	-----	---------

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))

×

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.

×

×

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).

×

b) Submission includes directions for use that

- include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND
- includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D

×

Comments?

(b)(4)

18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]

×

19) General labeling provisions

a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).

×

b) Labeling includes device common or usual name. (21 CFR 801.61)

×

20)

a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.

×

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

×

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	-----	----	-----	---------

c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.

Submission states that the device and/or accessories are: (one of the below must be checked)

☒ provided sterile

☐ provided non-sterile but sterilized by the end user

☐ non-sterile when used

☐ Information regarding the sterility status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	☒			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			☒	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	☒			
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	☒			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i>	☒			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.				
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☒			
e) Sterility Assurance Level (SAL) is stated.	☒			
24) If the device, and/or accessory, and/or a component is end user sterilized.			☒	

Elements of a Complete Submission (RTA Items)
Records processed under FOIA Request # 2022-07931 Released by JDR on 04/19/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

25)

a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.

×

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

×

c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

×

F. Shelf Life

26) Proposed shelf life/expiration date stated

×

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

×

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

×

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

×

Submission states that there: (one of the below must be checked)

× are direct or indirect (e.g., through fluid infusion) patient-contacting components.

are no direct or indirect (e.g., through fluid infusion) patient-contacting components.

Information regarding the patient contact status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Comments?

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present

×

30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)

×

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

31) Biocompatibility assessment of patient-contacting components

Submission includes:

Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR

a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).

×

H. Software

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

×

does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

×

does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

×

37)

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.

×

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

×

Elements of a Complete Submission (RTA Items)
Records Processed Under FOIA Request 2022-0093 Released by FOIA on 11/14/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

×

38) If literature is referenced in the submission, submission includes:

×

39) For each completed nonclinical (i.e., animal) study conducted

×

K. Performance Characteristics - In Vitro Diagnostic Devices Only
(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

is an in vitro diagnostic device.

×

is not an in vitro diagnostic device.

Decision: ☐ Accept ☒ **Refuse to Accept**

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off

Mario Mendoza -S
2013.09.03 11:34:11 -04'00'

Branch Chief Sign-Off
(digital signature optional)*

Lester W. Schultheis Jr
2013.09.04 10:38:09 -04'00'

Division Sign-Off
(digital signature optional)*



Tejashri Purohit-Sheth, M.D
Clinical Deputy Director
DAGRID

Tejashri S.
Purohitsheth -S
2013.09.04 12:18:06
-04'00'

* Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.

From: Suantak, Ngocinthawng * [Ngocinthawng.Suantak@fda.hhs.gov]
Sent: 9/10/2013 3:16:05 PM
To: drydenp@promedic.cc
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304/S002 Ack Letter
Attachments: K130304.pdf



Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 10, 2013

THE LARYNGEAL MASK CO.,LTD.
C/O TELEFLEX MEDICAL, INC.
2917 WECK DR
PO BOX 12600
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
ATTN: PAUL DRYDEN

510k Number: K130304

Product: LMA FAMILY OF AIRWAYS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul, Liz [mailto:liz.paul@teleflex.com]
Sent: Tuesday, January 28, 2014 2:10 PM
To: Mendoza, Mario; Paul Dryden
Cc: Lovelace, Justin
Subject: RE: K130304/S003 request for teleconference

That time will work for me.

Conference call information

Toll free: (b)(4)

International Access: (b)(4)

Conference Code: (b)(4)

Liz Paul | Director, RA/QE Anesthesia/Respiratory | Teleflex | Office: 919-433-8076 |
Cell: (b)(6) Liz.Paul@Teleflex.com<mailto:Liz.Paul@Teleflex.com>

From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Tuesday, January 28, 2014 2:07 PM
To: Paul Dryden
Cc: Paul, Liz; Lovelace, Justin
Subject: RE: K130304/S003 request for teleconference

Mr. Dryden,

We are available, 4-5pm EST today. Please advise.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document

to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Tuesday, January 28, 2014 8:36 AM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com<mailto:liz.paul@teleflex.com>); Lovelace, Justin (Justin.Lovelace@teleflex.com<mailto:Justin.Lovelace@teleflex.com>)

Subject: K130304/S003 request for teleconference

Dr. Mendoza:

We would like to have a conference call today, 1/28, any time between 1 - 2:30 or 4-5:00 EST, to discuss some of the questions and requests made 1/27 for K130304, the Teleflex LMA submission.

Since we are under a short timeline, we would appreciate your accommodating this request.

Participating would be

Liz Paul - Teleflex Director RA/QE Anesthesia/Respiratory

Justin Lovelace - Regulatory Affairs Specialist

Please confirm a time and we will set call a call in number.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

"The information contained in this message may be privileged, confidential, and protected from disclosure. If you are not the intended recipient, or an employee, or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting from your computer. Additionally, even if the intended recipient, any dissemination, distribution, or copying of this communication may still be prohibited if not previously understood and/or agreed upon by sender."

8 **Premarket Notification Truthful and Accuracy Statement**

[As Required by 21 CFR 807.87(k)]

I certify that in my capacity as Regulatory Affairs Manager of The Laryngeal Mask Company Limited , I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Sharon Wong
Regulatory Affairs Manager

01-Feb-13

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Review Memorandum

To: Mario Mendoza

From: Terry O. Woods, Ph.D.
WO 62-2116

Date: March 14, 2013

Re: K130304 Laryngeal Mask Company LMA Airways MR induced force, torque, and
artifact testing and labeling

**Terry O.
Woods**

Digitally signed by Terry O. Woods
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Terry O.
Woods,
0.9.2342.19200300.100.1.1=1300085350
Date: 2013.03.14 14:58:46 -04'00'

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

<u>20</u>	<u>Performance Testing</u>	<u>Page</u>
<u>20.1</u>	<u>Background of Bench Testing</u>	<u>2</u>
<u>20.2</u>	<u>Summary of ASTM F2052-02 Testing</u>	<u>2</u>
<u>20.3</u>	<u>Test Report LMA ProSeal™</u>	<u>9</u>
<u>20.4</u>	<u>Test Report LMA Flexible™</u>	<u>44</u>
<u>20.5</u>	<u>Test Report LMA Fastrach™ ETT</u>	<u>79</u>
<u>20.6</u>	<u>Test report LMA Supreme™</u>	<u>114</u>

20.1 Background of Bench Testing

The LMA™ airway products are very similar in the design, materials of construction and function.

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 identical to the LMA Supreme™ as they are of complete plastic, non-magnetic materials, except for the Check Valve, which is identical 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.

20.2 Summary of ASTM F2052-0e1 Testing

Testing was performed for

1. Static Magnetic Field – deflection
2. MRI-related heating
3. Artifact Information

(b)(4)

Fixation During Intended Use

During the intended use, it is 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 highlight that fixation in a MRI environment is mandated. The test reports discuss the testing in detail.

LMA ProSeal™

Non-clinical testing demonstrated that the LMA ProSeal™ is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

(b)(4)

LMA Classic Excel™

Non-clinical testing demonstrated that these devices are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

(b)(4)

LMA Flexible™

(b)(4)

Non-clinical testing demonstrated that these devices are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

(b)(4)

(b)(4)

LMA Fastrach™ ETT

Non-clinical testing demonstrated that these devices are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

(b)(4)

LMA Supreme™

Non-clinical testing demonstrated that the LMA Supreme™ is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

(b)(4)

20.3 Test Report LMA ProSeal™

**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA ProSeal, Size 5**

(b)(4)

REPORT
**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA ProSeal, Size 5**

Project Conducted by:

(b)(4)

06/09/10

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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20.4 Test report LMA Flexible™

**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Flexible, Size 6**

(b)(4)

REPORT
**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Flexible, Size 6**

Project Conducted by:

(b)(4)

06/08/10

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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20.5 Test report LMA Fastrach™ ETT

**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Fastrach, ETT Size 8**

(b)(4)

REPORT
**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Fastrach, ETT Size 8**

Project Conducted by:

(b)(4)

06/09/10

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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20.6 Test report LMA Supreme™

**Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Supreme, Size 5**

(b)(4)

REPORT
Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla
for the LMA Supreme, Size 5

Project Conducted by:

(b)(4)

06/07/10

Presented to:
Sharon Wong
Regulatory Manager
The Laryngeal Mask Company (Singapore) Pte. Ltd.
35 Joo Koon Circle, 4th Floor
Singapore 629110

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From: Suantak, Ngocinthawng * [Ngocinthawng.Suantak@fda.hhs.gov]
Sent: 9/10/2013 3:11:01 PM
To: drypen@promedic.cc
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304/S002 Ack Letter
Attachments: K130304.pdf



Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 10, 2013

THE LARYNGEAL MASK CO.,LTD.
C/O TELEFLEX MEDICAL, INC.
2917 WECK DR
PO BOX 12600
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
ATTN: PAUL DRYDEN

510k Number: K130304

Product: LMA FAMILY OF AIRWAYS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

21 Performance Testing – Animal

No animal performance testing was performed with the proposed device. Therefore this section is not applicable.

K 130304/S002

Teleflex

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

SEP 05 2013

Received

Teleflex Incorporated
2917 Weick Drive
P.O. Box 12500
Research Triangle Park
NC 27709
USA
www.teleflex.com

September 4, 2013

Subject: K130304 – Response to Refuse to Accept for LMA Airways for
MR Conditional use

Dear Dr. Mendoza:

This is response to the Refuse to Accept e-mail of 9/4/13 for K130304.

eCopy STATEMENT

In accordance with Section 745A(b) of the FD&C Act, we have prepared the eCopy of this submission.
It is an exact duplicate of the paper copy.

Per the instructions we are providing one (1) CD eCopy and one (1) hard copy.

We have addressed each deficiency as presented in the "Comments" section of the Refuse To Accept Checklist.

Please do not hesitate to contact me should you have any questions or require any additional information.

Sincerely,

(b)(6)

Paul Dryden
Regulatory consultant for Teleflex Medical

26

Table of Contents - Summary of Refuse to Accept items

Topic	Page
D (17)(a) – Labeling Indications for Use	3
Attachment # 1 – Indications for Use statement	4
Attachment # 2 – 510(k) Summary	9

D (17)(a) – Labeling and Indications for Use

(b)(4)

Attachment # 1 – Indications for Use statement

We have included Indications for Use statements for the following LMA products.

- LMA Classic™ (reusable)
- LMA Classic Excel™ (reusable)
- LMA Flexible™ (reusable)
- LMA Flexible™ Single Use
- LMA Unique™ Single Use

- LMA ProSeal™ (reusable)

- LMA Fastrach™ ETT (reusable)
- LMA Fastrach™ Single Use
- LMA Fastrach™ ETT Single Use

- LMA Supreme™ Single Use

Indications for Use Statement

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Indications for Use Statement

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Indications for Use Statement

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Indications for Use Statement

(b)(4)

Attachment # 2 – 510(k) Summary

Premarket Notification 510(k)
510(k) Summary

LMA MR Conditional

510(k) Summary

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<u>17</u>	<u>Biocompatibility</u>	<u>Page</u>
<u>17.1</u>	<u>Materials in Patient Contact</u>	<u>2</u>

17.1 Materials in Patient Contact

This submission does not relate to any change in materials for the LMA™ devices. Therefore we do not need to disclose the materials or provide a Material certification.

The materials in patient contact are identical to the Class 1 exempt predicate LMA™ airway devices or the Class 2 LMA Fastrach™ ETT and LMA Fastrach™ ETT Single Use.

Hi Mr. Dryden,

I will do my best to accommodate the times for today, I will need to have the MR consultant involved in the conversation. Once I can confirm with the MR consultant, then I will confirm with you for today or for later in the week.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Tuesday, January 28, 2014 8:36 AM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: K130304/S003 request for teleconference

Dr. Mendoza:

We would like to have a conference call today, 1/28, any time between 1 - 2:30 or 4-5:00 EST, to discuss some of the questions and requests made 1/27 for K130304, the Teleflex LMA submission.

Since we are under a short timeline, we would appreciate your accommodating this request.

Participating would be

Liz Paul - Teleflex Director RA/QE Anesthesia/Respiratory

Justin Lovelace - Regulatory Affairs Specialist

Please confirm a time and we will set call a call in number.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

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<u>15</u>	<u>Labeling</u>	<u>Page</u>
<u>15.1</u>	<u>Promotional Information</u>	<u>2</u>
<u>15.2</u>	<u>Other information</u>	<u>2</u>
<u>15.3</u>	<u>Proposed Labeling</u>	<u>2</u>

(b)(4)



COVER SHEET MEMORANDUM

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Mario Mendoza, MD

510(k) Number K130304/S004

Please list CTS decision code: SE - Substantially Equivalent

☐ Hold (Additional Information or Telephone Hold)

Hold Date

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

☐ Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

☐ Add to File

(review staff should follow the instructions and complete the memo/routing sheet at:

http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class: II
Regulation Number: 868.5730
Product Code: BTR
Additional Product Codes: CAE

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	×	
510(k) Summary or 510(k) Statement (<i>Attach Summary</i>)	×	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	×	
Is the device Class III?		×
Is this a combination product?		×
Is this device intended for pediatric use only?		×
Is this a prescription device? (If both prescription & OTC, check both boxes.)	×	
Is clinical data necessary to support the review of this 510(k)?		×
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		×
All Pediatric Patients age <= 21		×

Neonate/Newborn (Birth to 28 days)	Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024	×
Infant (29 days to < 2 years)		×
Child (2 years to <12 years)		×
Adolescent (12 years to <18 years)		×
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		×
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

Digital Signature Concurrence Table	
(Not all signatures may be required)	
Branch Chief Sign-Off	Todd D. Courtney -S 2014.05.30 09:57:17 -04'00'
Division Sign-Off	Tejashri S. Purohitsbeth -S Clinical Deputy Director Tejashri Purohit-Sheth, M.D. DAGRID/ODE/CDRH 2014.05.30 13:22:13 -04'00'

The Laryngeal Mask Company Limited

LMA™ Airways

TRADITIONAL 510(k)

5-Feb-13

Binder 1 of 1

OFFICIAL CORRESPONDENT

Kate Rizzo
c/o Teleflex Medical, Inc.
2917 Weck Drive
P.O. Box 12600
Research Triangle Park, NC 27709

Tel: 858-622-5621
Fax: 919-433-4996
E-mail: krizzo@lmana.com

<u>14</u>	<u>Comparison to Legally Marketed Predicate Devices</u>	<u>Page</u>
<u>14.1</u>	<u>Definitions</u>	<u>2</u>
<u>14.2</u>	<u>Discussion of the Comparison and Differences</u>	<u>2</u>
	<u>Table 14.1 Comparison to Predicate – CAE Classification</u>	<u>3</u>
	<u>Table 14.2 Comparison to Predicates – BTR Classification</u>	<u>4</u>
<u>14.3</u>	<u>Substantial Equivalence Comparison to Predicates</u>	<u>5</u>
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<u>14.5</u>	<u>Predicate Information</u>	<u>7</u>

14.1 Definitions

LMA makes a series of supraglottic airway devices. They are commonly referred to as LMAs yet we have several product families. We will use the following names throughout the submission:

- LMA
- LMA airway devices
- 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™

14.2 Discussion of the Comparison and Differences

This submission is seeking the addition of MR conditional environment of use for all of our LMA airway devices.

There have been no changes made to the devices we have only performed testing to demonstrate MR conditional compatibility.

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 have been and continued to be considered (b)(4) 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 tracheal tube, LMA Fastrach™ ETT tube, is considered a Class 2 device, for which we are seeking the same change in indications for use as MR conditional.

Table 14.1 – Comparison to Predicates - CAE Classification

(b)(4)

There are no differences between the proposed device and the predicate except we have performed testing to determine MR Conditional performance per ASTM F2502-06e1.

Table 14.2 Comparison to Predicates – BTR Classification

(b)(4)	
--------	--

There are no differences between the proposed device and the predicate except we have performed testing to determine MR Conditional performance per ASTM F2502-06e1.

14.3 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 –

- Identical 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 –

- Identical 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. (b)(4)

(b)(4)

Materials –

- There have been no changes in materials

Discussion: There are no differences in materials between the devices (b)(4)

(b)(4)

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.

Performance Testing

- Complies with ASTM F2502-06e1

Discussion: Testing has been performed according to ASTM F2052-06e1 for deflection in a 3.0 Tesla environment.

(b)(4)

Discussion of Classification – BTR

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

Indications –

- Identical 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 –

- Identical 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.

Performance Testing

- Complies with ASTM F2502-06e1

Discussion: Testing has been performed according to ASTM F2052-06e1 for deflection in a 3.0 Tesla environment.

(b)(4)

Substantial Equivalence Conclusion:

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

Bench testing per ASTM F2502-06e1 and requirements of fixing the device in place which is the normal use, the devices have been found safe and thus substantially equivalent.

14.4 Non-clinical Comparative Performance and Specifications

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: (b)(4)

(b)(4)

We have performed testing in accordance to ASTM F2052-06e1. The performance testing for MR conditions is presented in **Section 20 – Performance Testing - Bench.**

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 identical to the LMA Supreme™ as they are of complete plastic, non-magnetic materials, except for the Check Valve, which is identical 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.

14.5 Predicate Information

- LMA Classic™ - K904834
- LMA Fastrach™ ETT Reusable – K991580
- LMA Fastrach™ ETT Single Use – K051993

LMA Classic™ - K904834

Device Classification Name	<u>airway, oropharyngeal, anesthesiology</u> ²⁰
510(K) Number	K904834
Device Name	INTAVENT LARYNGEAL MASK
Applicant	INTAVENT INTL. S.A. st. andrews, abney ct dr. bourne end, bucks sl8 5dl england,
Contact	brain
Regulation Number	<u>868.5110</u> ²¹
Classification Product Code	<u>CAE</u> ²
Date Received	10/24/1990
Decision Date	07/26/1991
Decision	substantially equivalent (SE)
Classification Advisory Committee	Anesthesiology
Review Advisory Committee	Anesthesiology
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

LMA Fastrach™ ETT Reusable – K991580

FEB 4 2000

L991580

Attachment 1

510(k) Summary

§807.92(a)(1)

Submitter's Name:
C.L. McIntosh & Associates for The Laryngeal Mask Company Ltd.

Submitter's Address:
12300 Twinbrook Parkway
Suite 625
Rockville, MD 20852

Submitter's Telephone Number:
(301) 770-9590

Contact Person:
Robert L. Sheridan

Date of Preparation:
April 5, 1999

§807.92(a)(2)

Trade/Proprietary Name:
ILM Endotracheal Tube (ILM ETT)

Common/Usual Name:
Endotracheal Tube

Classification Name:
Tracheal Tube

§807.92(a)(3)

Legally Marketed Predicate Device:
Euromedical™ ILM (Intubating Laryngeal mask) 100% Silicone Wire-Reinforced Endotracheal Tube

§807.92(a)(4)

Description of Subject Device:
The ILM ETT is a straight, cuffed, wire-reinforced tracheal tube, with a Murphy Eye. It is available in a three sizes with internal diameters of 7.0mm, 7.5mm and 8.0mm.

The airway tube is made from silicone and features a stainless steel reinforcing wire to prevent kinking or occlusion of the tube. The tip of the tube is molded from a softer grade of silicone for passage through the vocal cords. The airway tube features an inflatable silicone cuff for sealing the tube in the trachea. The tip of the ILM ETT is beveled in two directions to aid passage of the tube through the trachea.

Depth markings are printed on the airway tube (in centimeters). These indicate the distance to the distal tip of the tube. The tube also has a printed black line to indicate its caudal surface.

The ILM ETT features a small diameter silicone tube connected to a pilot balloon with a luer check valve for inflation of the cuff.

The ILM ETT can be connected to the anesthesia circuit by a removable 15mm standard male connector which conforms to ISO5356-1 (1987). A connector is supplied with each ILM ETT.

The ILM ETT is designed to be compatible with the LMA-Fastrach (an oropharyngeal airway). To ensure compatibility, a marker line indicates when the tube passes through the LMA-Fastrach. In addition, the inflation line is mounted close to the rear of the ILM ETT to ensure unobstructed passage of the tube through the LMA-Fastrach.

§807.92(a)(5)

Statement of Intended Use:

The ILM ETT is indicated for airway management by oral intubation of the trachea.

§807.92(a)(6)

Comparison with Predicate Device:

The ILM ETT and the Euromedical Silicone Wire-Reinforced Endotracheal Tube have identical performance, and with the exception of the labeling, they are the same device. The two devices use the same materials and are dimensionally identical. They are molded and assembled in the same manufacturing plant to the same specifications (except for the labeling). The differences in the labeling are limited to changes in the company details, product names and attempts to make the Instructions for Use more readable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Mr. Robert L. Sheridan
The Laryngeal Mask Company Ltd.
c/o C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K991580
ILM Endotracheal Tube
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: November 5, 1999
Received: November 8, 1999

Dear Mr. Sheridan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

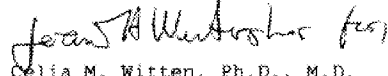
Section 14 – Substantial Equivalence Discussion

Page 2 – Mr. Robert L. Sheridan

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

Applicant: The Laryngeal Mask Company Ltd

510(k) Number (if known):

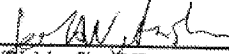
Device Name: ILM Endotracheal Tube

Indications for Use: The ILM Endotracheal Tube is indicated for airway management by oral intubation of the trachea.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use

(Per 21 CFR 801.109)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991580

LMA Fastrach™ ETT Single Use – K051993

DEC 13 2005

K051993

The Laryngeal Mask Company Limited

LMA Fastrach™ ETT SU

510(K) SUMMARY

Submitter:

The Laryngeal Mask Company Limited
PO Box 221, Mahe, Seychelles

**US Agent for Submission
And Contact Person:**

Mr. Foster Boop
LMA North America, Inc.
4660 La Jolla Village Drive
Suite 900
San Diego, CA 92122
Phone: 858-587-4025

Date Prepared:

04 July 2005

Trade Name:

LMA Fastrach™ ETT SU

Common Name:

Reinforced Tracheal Tube (Cuffed)

Device Type and Class:

Reinforced Tracheal Tube, Class II BTR,
21 CFR 868.5730

Predicate Device:

- Predicate 1: LMA Fastrach™ ETT already marketed in the USA under K991580
- Predicate 2: Sheridan Spiral-Flex ETT already marketed in the USA under K860105
- Predicate 3: Rusch Reinforced ETT already marketed in USA under K990619
- Predicate 4: Portex reinforced ETT already marketed in the USA under K032112

Device Description:

The LMA Fastrach™ ETT SU is a straight, cuffed, wire-reinforced, single use tracheal tube with a Murphy Eye. The metal wire spiral reinforcement is to provide kink-resistance. This type of product is typically used during operations where a high degree of flexibility is required from the tube, for instance prone position, head and neck surgery.

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The Laryngeal Mask Company Limited

LMA Fastrach™ ETT SU

510(K) SUMMARY

The plastic material and the spring allow the tube to be easily bent in all direction. The stainless steel reinforced wire prevent kinking or occlusion of the tube.

The cuff is intended to provide a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the tube and not allowed to escape to the patients upper airway, thus preventing loss of ventilation / anaesthetic, and reducing the likelihood of any aspirated stomach contents from entering the lungs.

This reinforced tracheal tube is available in size 6, 6.5, 7.0, 7.5 and 8.0 mm only. And it is designed to be compatible with the LMA Fastrach™, LMA Fastrach™ Single Use and LMA CTrach™ Airways.

Intended Use:

The LMA Fastrach™ ETT SU is intended to be used for oral intubation for airway management during anaesthesia. The product maybe used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

Technological Characteristics of the Proposed Versus Predicate Devices:

The proposed device is substantially equivalent to predicate 1 – LMA Fastrach™ ETT, in all aspects except the followings:

- **Material.** The proposed device is identical in material to the tubing used in Predicate 2: Sheridan Spiral-Flex ETT, Predicate 3: Rusch Reinforced ETT and Predicate 4: Portex reinforced ETT.
- **Sterile.** The proposed device is a sterile single use device which is identical to the Predicate 4- Portex reinforced ETT and Predicate 2- Sheridan Spiral-Flex ETT.
- **Cuff.** The proposed device is identical in material and design to that of Predicate 2- Sheridan Spiral-Flex ETT.

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The Laryngeal Mask Company Limited

LMA Fastrach™ ETT SU

510(K) SUMMARY

Performance / Clinical Data:

Clinical evaluation data is shown in Section 6.

Conclusion:

Comparison of the proposed device to the predicate devices supports the conclusion that the proposed device is substantially equivalent in safety and effectiveness in its intended use to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Laryngeal Mask Company Limited
C/O Mr. Foster Boop
Director, Technical Affairs
LMA North America, Incorporated
9360 Towne Centre Drive
San Diego, California 92121

Re: K051993
Trade/Device Name: LMA Fastrach™ ETT Single Use
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: December 2, 2005
Received: December 5, 2005

Dear Mr. Boop:

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.

Page 2 – Mr. Boop

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 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

Indications for Use

510(k) Number (if known): K051993

Device Name: LMA Fastrach™ ETT Single Use

The LMA Fastrach™ ETT SU is intended to be inserted through the patient's mouth into the trachea to maintain an open airway and is attached to the anaesthetic machine via a connector after insertion into the patient. It is intended that following the insertion, the user will be able to inflate the device cuff and ventilate the patient.

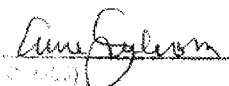
Indications for Use:

The LMA Fastrach™ ETT SU 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Amy S. Glick, General Hospital,
Air Control, Dental Devices
K051993

Page 1 of 1

06 **Indications for Use Statement**

As required, we have prepared the Indications for Use statement for each of the product classifications as part of the bundled submission.

Indications for Use Statement

(b)(4)

Indications for Use Statement

(b)(4)

Dear Mr. Dryden:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Please let me know if you have any questions.

Sincerely,

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.



24301 Woodsage Drive
Bonita Springs, FL 34134-2958
Tel (239) 498-2155 ~ Fax (239) 236-0354
E-mail - drydenp@promedic.cc

MEMORANDUM

FROM: Paul E. Dryden – ProMedic, Inc. (b)(6)
SUBJECT: FDA communications for K130304 – Teleflex LMA for MR use

28-Jan-14

Call started 4:03 PM EST

FDA

Mario Mendoza, MD and Dan Krainak, PhD

Teleflex

Liz Paul – Director – RA/QE Anesthesia / Respiratory

Justin Lovelace – Regulatory Affairs Specialist

Paul Dryden – ProMedic, Inc. – consultant

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Classic™, Classic™ Excel, Unique™ and Flexible™

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Todd D. Courtney-S
2014.07.02 15:58:19 -04'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Fastrach™

Indications for Use (Describe)

The LMA Fastrach™ is indicated for use in achieving and maintaining control of the airway during anticipated or unanticipated difficult airways and emergency anesthetic procedures using either spontaneous or Positive Pressure Ventilation (PPV). LMA Fastrach™ is also intended for use as a rescue device in emergency situations.

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.

- 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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Fastrach™ ETT

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA Supreme

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K130304

Device Name

LMA ProSeal

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CONSULTING MEMO

Date: May 28, 2014

To: Mario Mendoza, M.D., M.S.
CDRH/ODE/DAGRID/ANDB

From: Daniel Krainak, PhD
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

Subject: K130304/S004
Laryngeal Mask Airways (LMAs)
Laryngeal Mask Company

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

V. Signatures

A handwritten signature in black ink, appearing to read 'D. Krainak', is positioned to the left of the printed name and timestamp.

Daniel M. Krainak

2014.05.28 09:28:32 -04'00'

Mario R. Mendoza, M.D., MS
FDA Commissioner's Fellow
CDRH/ODE/DAGRID/ANDB
WO66, Room 2523
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Mario Mendoza [mailto:mario.mendoza@fda.hhs.gov]
Sent: Friday, February 22, 2013 4:50 PM
To: KRIZZO@LMANA.COM
Cc: Mendoza, Mario
Subject: K130304 was Refused

February 22, 2013

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K130304. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response, referencing the 510(k) number K130304, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Mario Mendoza, the lead reviewer assigned to your 510(k) submission.

I understand the issue, so I will try my best to get the MR consultant (who is also critical) to be available today.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]

Sent: Tuesday, January 28, 2014 11:07 AM

To: Mendoza, Mario

Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)

Subject: RE: K130304/S003 request for teleconference

Thank you but according to your email we must respond by 1/31, so there is not much time. Also Ms. Paul is traveling and may not be available and it is critical that she is part of the call.

Paul

Always with a handshake,

Paul Dryden

ProMedic, Inc.

24301 Woodsage Dr.

Bonita Springs, FL 34134-2958

T - +239-498-2155

M - (b)(6)

F - + 239-236-0354

E - drydenp@promedic.cc<mailto:drydenp@promedic.cc>

"The information contained in this message may be privileged, confidential, and protected from disclosure. If you are not the intended recipient, or an employee, or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is

strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting from your computer. Additionally, even if the intended recipient, any dissemination, distribution, or copying of this communication may still be prohibited if not previously understood and/or agreed upon by sender."

From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]

Sent: Tuesday, January 28, 2014 11:03 AM

To: Paul Dryden

Subject: RE: K130304/S003 request for teleconference

Hi Mr. Dryden,

I will do my best to accommodate the times for today, I will need to have the MR consultant involved in the conversation. Once I can confirm with the MR consultant, then I will confirm with you for today or for later in the week.

Mario Mendoza, M.D.

Medical Officer

FDA/CDRH/ODE/DAGRID/ANDB

10903 New Hampshire Avenue

White Oak, Bldg 66, Room 2563

Silver Spring, MD 20993

Email: Mario.Mendoza@fda.hhs.gov<mailto:Mario.Mendoza@fda.hhs.gov>

Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

10 Financial Certification or Disclosure Statement

This submission for the family of LMA™ Airways does not included clinical data in this submission and therefore Forms 3454 and 3455 for investigator certification and disclosure are not required.



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.

Page 2 – Mr. Dryden

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



24301 Woodsage Drive
Bonita Springs, FL 34134-2958
Tel (239) 498-2155 ~ Fax (239) 236-0354
E-mail - drydenp@promedic.cc

MEMORANDUM

FROM: Paul E. Dryden – ProMedic, Inc. (b)(6)
SUBJECT: FDA communications for K130304 – Teleflex LMA for MR use

28-Jan-14

Call started 4:03 PM EST

FDA

Mario Mendoza, MD and Dan Krainak, PhD

Teleflex

Liz Paul – Director – RA/QE Anesthesia / Respiratory

Justin Lovelace – Regulatory Affairs Specialist

Paul Dryden – ProMedic, Inc. – consultant

(b)(4)

(b)(4)

(b)(4)

From: Napper, Jesse * [Jesse.Napperli@fda.hhs.gov]
Sent: 2/8/2013 3:21:46 PM
To: KRIZZO@LMANA.COM
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304 ACK LETTER
Attachments: CrystalViewer[11].rtf



Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 08, 2013

THE LARYNGEAL MASK CO.,LTD.
C/O TELEFLEX MEDICAL, INC.
2917 WECK DR
PO BOX 12600
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
ATTN: KATE RIZZO

510k Number: K130304

Received: 2/7/2013

Product: LMA FAMILY OF AIRWAYS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K130304

Date Received by DCC: Sep 5, 2013

Lead Reviewer: Anh Nguyen, M.D., MBA

Branch: ANDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed

Yes

No

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

×

Comments?

2. Is the application with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."

×

Comments?

3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question is no, mark "No." If there was no RFD, skip this question.

Comments?

4) Is this device type eligible for a 510(k) submission?

If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."

×

Comments?

5) Is there a pending PMA for the same device with the same indications for use?

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.

X

Comments?

6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm>

X

Comments?

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)
Revised Process and Order Form Request for Pre-Submission Review on 4/10/24
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	×			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	×			
a) Device trade name or proprietary name	×			
b) Device common name	×			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	×			
4) Submission contains 510(k) Summary or 510(k) Statement	×			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	×			
b) Statement contains all elements per 21 CFR 807.93			×	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format.	×			
6) Submission contains Class III Summary and Certification. See recommended content.	×			
7) Submission contains clinical data			×	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	×			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	×			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	×			

B. Device Description

10)	
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Elements of a Complete Submission (RTA Items)

Records processed under FOIA Request # 2022-0001 Released by DOR on 04/10/2024

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	×			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×			
c) A list and description of each device for which clearance is requested.	×			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	×			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	×			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	×			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	×			

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	×			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	×			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	×			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	×			
b) Technology, including features, materials, and principles of operation	×			

Elements of a Complete Submission (RTA Items)

Revised Process and Order Form Request for RTA (2021) Released by FDA on 11/19/24

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))

×

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.

×

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).

×

b) Submission includes directions for use that

- include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND
- includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D

×

18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also [Alternative to Certain Prescription Device Labeling Requirements](#)]

×

19) General labeling provisions

a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).

×

b) Labeling includes device common or usual name. (21 CFR 801.61)

×

20)

a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.

×

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

×

c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

×

21) If the device is an *in vitro* diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10

×

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Elements of a Complete Submission (RTA Items)
Regulation Process under PMA Request 2020-001 Released by FDA on 4/10/2024
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.

Submission states that the device and/or accessories are: (one of the below must be checked)

✕

provided sterile

provided non-sterile but sterilized by the end user

non-sterile when used

Information regarding the sterility status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

22) Assessment of the need for sterilization information

a) Identification of device, and/or accessories, and/or components that are provided sterile.

✕

b) Identification of device, and/or accessories, and/or components that are end user sterilized.

✕

c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.

✕

23) If the device, and/or accessory, and/or a component is provided sterile:

a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).

✕

b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*

✕

c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.

d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)

✕

e) Sterility Assurance Level (SAL) is stated.

✕

24) If the device, and/or accessory, and/or a component is end user sterilized:

✕

25)

a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.

✕

Elements of a Complete Submission (RTA Items)
Revised Process and Under PMA Request 2022-2023 Released by FDA on 4/10/24
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	------------	-----------	------------	----------------

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

×

c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

×

F. Shelf Life

26) Proposed shelf life/expiration date stated

×

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

×

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

×

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

Submission states that there: (one of the below must be checked)

× are direct or indirect (e.g., through fluid infusion) patient-contacting components.

are no direct or indirect (e.g., through fluid infusion) patient-contacting components.

Information regarding the patient contact status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present

×

30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)

×

31) Biocompatibility assessment of patient-contacting components

Submission includes:

Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR

a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).

×

H. Software

Elements of a Complete Submission (RTA Items)

Revised Process and Form Request 2022-09-01 Released by FDA on 11-14-2024

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	-----	----	-----	---------

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

✗ does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

✗ does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

✗

37)

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.

✗

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

✗

c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

✗

38) If literature is referenced in the submission, submission includes:

✗

39) For each completed nonclinical (i.e., animal) study conducted

✗

Questions: Contact FDA/CDRH/DOH-108 at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

☐ is an in vitro diagnostic device.

☒ is not an in vitro diagnostic device.

Decision:☒ **Accept**☐ **Refuse to Accept**

Records processed under FOIA Request 2024-6295; Released by CDRH on 11-14-2024

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off

**Anh T.
Nguyen**Digitally signed by Anh T. Nguyen
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
cn=Anh T. Nguyen,
0.9.2342.19200300.100.1.1=200081
9081
Date: 2013.09.16 13:29:33 -04'00'Branch Chief Sign-Off
(digital signature
optional)***Lester W. Schultheis Jr**
2013.09.17 15:40:04 -04'00'Division Sign-Off
(digital signature
optional)** Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.

Mario R. Mendoza, M.D., MS
Medical Officer
CDRH/ODE/DAGRID/ANDB
WO66, Room 2563
Office: (240) 402-5121
Mario.Mendoza@fda.hhs.gov

From: Paul, Liz [mailto:liz.paul@teleflex.com]
Sent: Tuesday, January 28, 2014 2:10 PM
To: Mendoza, Mario; Paul Dryden
Cc: Lovelace, Justin
Subject: RE: K130304/S003 request for teleconference

That time will work for me.

Conference call information

Toll free: (b)(4)
International Access: (b)(4)
Conference Code: (b)(4)

Liz Paul | Director, RA/QE Anesthesia/Respiratory | Teleflex | Office: 919-433-8076 | Cell: 919-597-9722 | Liz.Paul@Teleflex.com

From: Mendoza, Mario [mailto:Mario.Mendoza@fda.hhs.gov]
Sent: Tuesday, January 28, 2014 2:07 PM
To: Paul Dryden
Cc: Paul, Liz; Lovelace, Justin
Subject: RE: K130304/S003 request for teleconference

Mr. Dryden,
We are available, 4-5pm EST today. Please advise.
Mario Mendoza, M.D.
Medical Officer
FDA/CDRH/ODE/DAGRID/ANDB
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2563
Silver Spring, MD 20993
Email: Mario.Mendoza@fda.hhs.gov
Phone: 240.402.5121

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Paul Dryden [mailto:drydenp@promedic.cc]
Sent: Tuesday, January 28, 2014 8:36 AM
To: Mendoza, Mario
Cc: Paul, Liz (liz.paul@teleflex.com); Lovelace, Justin (Justin.Lovelace@teleflex.com)
Subject: K130304/S003 request for teleconference

Dr. Mendoza:

We would like to have a conference call today, 1/28, any time between 1 - 2:30 or 4-5:00 EST, to discuss some of the questions and requests made 1/27 for K130304, the Teleflex LMA submission.

Since we are under a short timeline, we would appreciate your accommodating this request.

Participating would be

Liz Paul – Teleflex Director RA/QE Anesthesia/Respiratory
Justin Lovelace – Regulatory Affairs Specialist

Please confirm a time and we will set call a call in number.

Paul

Always with a handshake,

Paul Dryden
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958
T - +239-498-2155
M - (b)(6)
F - +239-236-0354
E -- drydenp@promedic.cc

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From: Pugh, Dominique * [Dominique.Pugh@fda.hhs.gov]
Sent: 8/21/2013 2:37:26 PM
To: drydenp@promedic.cc
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K130304/S001 ACK LETTER
Attachments: K130304-S001.pdf



Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 21, 2013

THE LARYNGEAL MASK CO.,LTD.
C/O TELEFLEX MEDICAL, INC.
2917 WECK DR
PO BOX 12600
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
ATTN: PAUL DRYDEN

510k Number: K130304

Product: LMA FAMILY OF AIRWAYS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff