

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.

## 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.

## **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.



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.


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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" (21CFR 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.

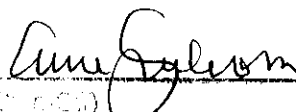
Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (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)



Chief, ODE  
Medical Technology, General Hospital,  
Device Control, Dental Devices

Number: K051993