April 29, 2025

Teleflex Medical
Irma Govea
Regulatory Affairs Specialist
3015 Carrington Mills Blvd
Morrisville, North Carolina 27560

Re: K242495
Trade/Device Name: LMA Fastrach ETT SU
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: April 2, 2025
Received: April 2, 2025

Dear Irma Govea:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242495

Device Name

LMA Fastrach ETT SU

Indications for Use *(Describe)*

The LMA® Fastrach™ ETT Single Use is indicated for tracheal intubation through the LMA® Fastrach™.

The Stabiliser Rod is indicated for use during removal of the LMA® Fastrach™ and LMA® Fastrach™ Single Use after intubation to keep the LMA® Fastrach ™ ETT Single Use in place.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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510(k) Summary

A. Name, Address, Phone and Fax Number of Applicant
Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 1 919-361-3973

B. Contact Person
Irma Govea
Regulatory Affairs Specialist

C. Date Prepared
March 31, 2025

D. Device Name
Subject Device 1

Trade Name:	LMA Fastrach™ ETT SU
Common Name:	Endotracheal Tube
Product Code:	BTR
Regulation Number:	21 CFR 868.5730
Classification Name:	Tube, Tracheal (W/Wo Connector)
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device
K051993 LMA Fastrach ETT SU

F. Device Description
The LMA® Fastrach™ ETT Single Use has been developed specifically for use with the LMA® Fastrach™. It is a straight, cuffed, wire-reinforced tube with a Murphy Eye and a standard 15mm connector.

The LMA® Fastrach™ ETT Single Use has a pilot balloon with a luer check valve and a unique, soft, moulded tip for atraumatic passage through the vocal cords. As a reference during intubation, the LMA® Fastrach™ ETT Single Use has depth markers to indicate the distance to the distal tip of the LMA™ airway. The LMA® Fastrach™ ETT Single Use is radiopaque along its full length and its tip is made out of a radio opaque material to enhance its visibility in x-rays.

Accessory device: The Stabiliser Rod Single Use is an accessory and it is indicated for use during removal of the reusable LMA® Fastrach™ and LMA® Fastrach™ Single Use after intubation to keep the Endotracheal Tube (ETT) in place.

G. Indications for Use
See Substantial Equivalence Table Below

H. Contraindications

The **LMA® Fastrach™ ETT Single Use** 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.

There are no known contraindications associated with the **Stabiliser Rod** accessory device.

I. Substantial Equivalence

The subject device is substantially equivalent to the predicate device with respect to intended use, technology, and design. The differences between the predicate and the subject devices are minor and any risks have been mitigated through testing. The table below summarizes the differences between the subject and predicate device.

Table 1. Substantial Equivalence Comparative Table LMA Fastrach ETT SU

Features	Teleflex Medical LMA Fastrach ETT SU	Teleflex Medical LMA Fastrach ETT SU (Predicate K051993)	Comments
Classification Name	Tube, Tracheal (w/wo connector)	Same	Same
Product Code	BTR	Same	Same
Regulation Number	868.5730	Same	Same
Indications for Use	The LMA® Fastrach™ ETT Single Use is indicated for tracheal intubation through the LMA® Fastrach™. The Stabiliser Rod is indicated for use during removal of the LMA® Fastrach™ and LMA® Fastrach™ Single Use after intubation to keep the LMA® Fastrach ™ ETT Single Use in place.	The LMA Fastrach™ ETT SU is indicated for airway management by oral intubation on 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.	Indication is not changing; a rewording was made for better readability
Patient Population	LMA® Fastrach™ ETT Single Use is intended for patients who require intubation through the Fastrach LMA to facilitate oxygenation and ventilation. Clinical judgement should be used in the selection of the appropriate device size for an individual patient.	Not stated	Although predicate device does not clearly state the patient population in the IFU, it remains the same for both products
Contraindications	The LMA® Fastrach™ ETT Single Use should not be placed	LMA Fastrach ETT is contraindicated in procedures	Contraindications are not

	in patients eligible for procedures which involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device. There are no known contraindications associated with the LMA ® Fastrach™ Stabiliser Rod accessory device.	which involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device.	changing; a rewording was made for better readability A statement has been added for the stabilizer rod, even though there are no known contraindications
Single Use	Yes	Same	Yes
Size Range	6.0 mm – 8.0 mm	Same	Same
Cuffed	Yes	Same	Same
Radiopaque	Yes	Same	Same
Connection to ventilation source	15 mm connector Polyamide	15 mm connector Polypropylene (PP)	Materials have been tested per ISO 10993-1
Method of Sterilization	Ethylene Oxide 10^{-6} SAL	Same	Same
Biocompatibility	Materials have been tested per ISO 10993-1	Materials biocompatible	Materials have been tested per ISO 10993-1
Components & Materials	Main tube – Non-DEHP Polyvinylchloride (PVC) reinforced with Stainless Steel Cuff – PVC Boat tip – PVC Inflation line – PVC Ink – Black Ink + Reducer Stabilizer rod - PVC	Main tube – Polyvinylchloride (PVC) reinforced with Stainless Steel Cuff -PVC Boat tip – PVC Inflation line – PVC Ink – Black Ink Stabilizer rod - PVC	Materials were changed to non-DEHP
Sterile	Yes	Same	Same
Eye	Murphy	Same	Same
Graduations	Multiple cm markings	Same	Same
MR Safety	MR Conditional	Not declared	Testing has been conducted
Shelf-life	1 year	2 years	Testing has been conducted

Packaging	Preformed pouch Packaging film – PET/EP 12/60 Tyvex – Uncoated Tyvex Paper 1073B	Blister tray Packaging film – Perfecseal 30652-EE (8 mil) nylon film Tyvex – PerfecSeal 2FS Tyvex heat seal coated with SBP 2000	Packaging performance testing was conducted

J. Comparison to the Predicate

The table above illustrates the similarities and differences between the subject and predicate device. **The basic technological and operating principles are the same for both devices**. Both the subject and predicate devices are for airway management. Both the subject and predicate devices are disposable, sterile, single patient use devices. The subject devices are substantially equivalent to the predicate device. There are no significant differences that would affect safety and efficacy.

K. Performance Data

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Testing performed included visual inspection, dimensional testing, bonding strength (main tube with boat tip, side arm, 15mm connector and cuff bonding), kink resistance, cuff herniation, resistance to collapse, tracheal seal testing.

The testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device.

The LMA Fastrach ETT SU passed all evaluations and tests. The device is biocompatible and meets the requires pertaining to biocompatibility per 10993-1, ISO 18562-1, the US FDA Guidance on Application of 10993-1.

L. Conclusion

The subject device has the same intended use and technological characteristics and construction as the predicate. Test results demonstrate that the subject device meets it's intended use. It is for these reasons that the subject device can be found substantially equivalent to the predicate devices.