

K242495 LMA Fastrach ETT SUApr 29, 2025
250 days to decisionK242495 · Product code: **BTR** · Anesthesiology
Source: <https://www.510kdatabase.net/k242495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Aug 22, 2024
Decision date	Apr 29, 2025
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	Irma Govea
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...