

K153470 MADgic Laryngo-Tracheal Mucosal Atomization Device

Aug 19, 2016
261 days to decisionK153470 · Product code: **CCT** · Anesthesiology
Source: <https://www.510kdatabase.net/k153470/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Applicator (laryngo-tracheal), Topical Anesthesia (CCT)
Date received	Dec 2, 2015
Decision date	Aug 19, 2016
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	Kristen Bisanz
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...

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Device record: <https://www.510kdatabase.net/k153470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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