

K243785 Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced

Sep 25, 2025
290 days to decision

K243785 · Product code: BTR · Anesthesiology
Source: <https://www.510kdatabase.net/k243785/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Dec 9, 2024
Decision date	Sep 25, 2025
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Shruti Shah
510(k) history	88 submissions · 85 cleared · 2010-2026
