

K250173 Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye (113-XX) Shiley™ Nasal RAE Tracheal Tube Cuffless, Murphy Eye (114-XX) Shiley™ Oral RAE Tracheal Tube Cuffed, Murphy Eye (115-XX) Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (115-XXOR) Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (119-XXNR)

Oct 6, 2025
258 days to decision

K250173 · Product code: **BTR** · Anesthesiology
Source: <https://www.510kdatabase.net/k250173/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Jan 21, 2025
Decision date	Oct 6, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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