

K251313 Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Distal with Disposable Inner CannulaDec 29, 2025
245 days to decisionK251313 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k251313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Apr 28, 2025
Decision date	Dec 29, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Proximal with Disposable Inner Cannula; Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Distal with Disposable Inner Cannula ; Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Proximal with Disposable Inner Cannula; Shiley™ Adult Flexible Disposable Inner Cannula XLT

APPLICANT

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

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