

**K142296 Shiley Adult Flexible Tracheostomy Tube Cuffless,
Disposable Inner Cannula**Feb 24, 2015
190 days to decisionK142296 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k142296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Aug 18, 2014
Decision date	Feb 24, 2015
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary
Other names	Shiley Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	Danielle Mueller
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k142296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026