

**K003315 SHILEY TRACHEOSOFT XLT EXTENDED LENGTH  
TRACHEOSTOMY TUBE AND DISPOSABLE INNER CANNULA**Nov 8, 2000  
16 days to decisionK003315 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k003315/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Oct 23, 2000
Decision date	Nov 8, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mallinckrodt, Inc.</b>
Location	St. Louis, MO, US
Contact	JAMES C KEEVEN
510(k) history	2 submissions · 1 cleared · 2000-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003315/> 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 25, 2026