

**K945406 SSV PHONATE(TM) SHILEY SPEAKING VALVE**Feb 27, 1995  
116 days to decisionK945406 · Product code: **BTO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k945406/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Nov 3, 1994
Decision date	Feb 27, 1995
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mallinckrodt Medical Tpi, Inc.</b>
Location	Irvine, CA, US
Contact	ROBERT F INGHAM
510(k) history	4 submissions · 4 cleared · 1993-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945406/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026