

**K945407 SSVO PHONATE(TM) SHILEY SPEAKING VALVE WITH OXYGEN PORT**Feb 27, 1995  
116 days to decisionK945407 · Product code: **BTO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k945407/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945407/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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