

**K944451 PASSY-MUIR TRACHEOSTOMY SPEAKING VALVES
(ONE-WAY TRACHEOSTOMY SPEAKING VALVES)**Jul 7, 1995
298 days to decisionK944451 · Product code: JOH · Anesthesiology
Source: <https://www.510kdatabase.net/k944451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Sep 12, 1994
Decision date	Jul 7, 1995
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Passy-Muir, Inc.
Location	Irvine, CA, US
Contact	PATRICIA E PASSY
510(k) history	5 submissions · 5 cleared · 1995-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944451/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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