

K962714 PASSY-MUIR LOW-PROFILE TRACHEOSTOMY AND VENTILATOR SPEAKING VALVEOct 28, 1996
108 days to decisionK962714 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k962714/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Jul 12, 1996
Decision date	Oct 28, 1996
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement
Other names	PRODUCT NUMBER PMV 2000 OR PMTSV 2000

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/k962714/> 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