

**K990905 PASSY-MUIR LOW-PROFILE TRACHEOSTOMY  
SPEAKING VALVE PMV 2020 (CLEAR) JIT**Jun 11, 1999  
85 days to decisionK990905 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k990905/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Mar 18, 1999
Decision date	Jun 11, 1999
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990905/> 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