

K911080 HYGIENA-TRACHMay 20, 1991
70 days to decisionK911080 · Product code: **JOH** · AnesthesiologySource: <https://www.510kdatabase.net/k911080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Mar 11, 1991
Decision date	May 20, 1991
Days to decision	70 days
Third-party review	No

APPLICANT

Company	Apdyne Medical Co.
Location	Saint Paul, MN, US
Contact	MICHAEL W WALSH
510(k) history	2 submissions · 1 cleared · 1989-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911080/>, 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 26, 2026