

K912124 TRACHEOSTOMY TUBE AND CUFFAug 16, 1991
95 days to decisionK912124 · Product code: **BTO** · Anesthesiology
Source: <https://www.510kdatabase.net/k912124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	May 13, 1991
Decision date	Aug 16, 1991
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Concord/Portex
Location	Keene, NH, US
Contact	ROBERT WHEELER
510(k) history	23 submissions · 20 cleared · 1989-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912124/> 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