

K964722 DELTA N95 RESPIRATORFeb 7, 1997
74 days to decisionK964722 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k964722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 25, 1996
Decision date	Feb 7, 1997
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Racal Filter Technologies, Inc.
Location	Brockville, Ontario, CA
Contact	JOHN CAMPBELL
510(k) history	2 submissions · 2 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964722/> 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 July 6, 2026