

K914088 BIVONA AIRE-CUF(R) PEDIATRIC TRACHEOSTOMY TUBEOct 23, 1991
42 days to decisionK914088 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k914088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Sep 11, 1991
Decision date	Oct 23, 1991
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bivona Medical Technologies
Location	Mchenry, IL, US
Contact	HARRY M KAUFMAN
510(k) history	50 submissions · 50 cleared · 1978-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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