

K944178 BIVONA FLEXTEND PEDIATRIC & NEONATAL TRACHEOSTROMY TUBESOct 27, 1994
62 days to decisionK944178 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k944178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Aug 26, 1994
Decision date	Oct 27, 1994
Days to decision	62 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/k944178/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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