

K894614 BIVONA AIRE-CUF ADJUSTABLE TRACHEOSTOMY TUBEOct 13, 1989
85 days to decisionK894614 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k894614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Jul 20, 1989
Decision date	Oct 13, 1989
Days to decision	85 days
Third-party review	No

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/k894614/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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