

K894613 BIVONA FOME-CUF ADJUSTABLE TRACHEOSTOMY TUBEOct 13, 1989
85 days to decisionK894613 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k894613/>**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.net

Device record: <https://www.510kdatabase.net/k894613/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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