

**K896547 MODIFIED FOME-CUF SILICONE TRACHEOSTOMY TUBE**Jan 22, 1990  
68 days to decisionK896547 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k896547/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Tube Tracheostomy And Tube Cuff (JOH) |
| Date received         | Nov 15, 1989                          |
| Decision date         | Jan 22, 1990                          |
| Days to decision      | 68 days                               |
| Third-party review    | No                                    |

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896547/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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