

**K964056 RUSCH ULTRA TRACHEOFLEX FENESTRATED KIT  
CUFFED,UNCUFFED/ RUSCH TRACHEOFLEX  
TRACHEOSTOMY KIT UNCUFFED STERILE**Oct 10, 1997  
366 days to decisionK964056 · Product code: JOH · Anesthesiology  
Source: <https://www.510kdatabase.net/k964056/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Oct 9, 1996
Decision date	Oct 10, 1997
Days to decision	366 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rusch Intl.</b>
Location	Jeffrey, NH, US
Contact	NEIL R ARMSTRONG
510(k) history	43 submissions · 43 cleared · 1995-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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