

K122235 RUSCH TRACFLEX PLUS TRACHEOSTOMY TUBE SETSep 6, 2013
407 days to decisionK122235 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k122235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Jul 26, 2012
Decision date	Sep 6, 2013
Days to decision	407 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	LORI PFOHL
510(k) history	64 submissions · 61 cleared · 1985-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122235/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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