

K151404 ProTrach DualcareFeb 12, 2016
262 days to decisionK151404 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k151404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	May 26, 2015
Decision date	Feb 12, 2016
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Atos Medical AB
Location	Potomac, MD, US
Contact	Ferenc Dahner
510(k) history	15 submissions · 14 cleared · 1990-2016

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