

K173384 BLUselect, non-fenestrated, BLUselect, non-fenestrated, cont, BLUselect, fenestrated, BLUselect Suctionaid, BLUpere Dilation Trachestomy Kit, without tube

Apr 10, 2018
162 days to decision

K173384 · Product code: **BTO** · Anesthesiology
Source: <https://www.510kdatabase.net/k173384/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Oct 30, 2017
Decision date	Apr 10, 2018
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smiths Medical Ads, Inc.
Location	Plymouth, MN, US
Contact	Donna M. Semlak
510(k) history	2 submissions · 2 cleared · 2017-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k173384/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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