

K173912 BLUperc Percutaneous Dilation Tracheostomy Kit with BLUselect tube, BLUperc Percutaneous Dilation Tracheostomy Kit with BLUselect Suctionaid tube, BLUgriggs Percutaneous Dilation Tracheostomy Kit with BLUselect tube, BLUgriggs Percutaneous Dilation Tracheostomy Kit with BLUselect Suctionaid tubeMay 8, 2018
137 days to decisionK173912 · Product code: JOH · Anesthesiology
Source: <https://www.510kdatabase.net/k173912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Dec 22, 2017
Decision date	May 8, 2018
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smiths Medical Asd, Inc.
Location	Rockland, MA, US
Contact	Donna M. Semlak
510(k) history	52 submissions · 52 cleared · 2004-2024

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