

**K083031 PORTEX UNIPERC PERCUTANEOUS DILATION  
TRACHEOSTOMY KIT**Aug 18, 2009  
312 days to decisionK083031 · Product code: **BTO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k083031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Oct 10, 2008
Decision date	Aug 18, 2009
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smiths Medical Asd, Inc.</b>
Location	Rockland, MA, US
Contact	JOHN TULLETT
510(k) history	52 submissions · 52 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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