

**K190878 Trach- Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip and Salter ThinCuff, Trach- Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip and Salter ThinCuff**Jan 10, 2020  
281 days to decisionK190878 · Product code: **BTR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k190878/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Apr 4, 2019
Decision date	Jan 10, 2020
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Salter Labs, Inc.</b>
Location	Carlsbad, CA, US
Contact	Mara Caler
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Salter Labs</b>
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190878/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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