

**K192511 Venner PneuX™ TT (Tracheostomy Tube) Size 7.0 mm,
Venner PneuX™ TT (Tracheostomy Tube) Size 8.0 mm, Venner
PneuX™ TT (Tracheostomy Tube) Size 9.0 mm**Jul 22, 2020
314 days to decisionK192511 · Product code: **BTO** · Anesthesiology
Source: <https://www.510kdatabase.net/k192511/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Sep 12, 2019
Decision date	Jul 22, 2020
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Venner Medical (Singapore) Pte, Ltd.
Location	Dallas, TX, US
Contact	Adrian P Waterton
510(k) history	6 submissions · 6 cleared · 2010-2020

REGULATORY CONSULTANT

Consulting firm	Brauer Device Consultants, LLC
Contact	Christine Brauer

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

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