CLEARED

K192120 Venner PneuX™ ETT (Endotracheal Tube) 6 mm, Venner PneuX™ ETT (Endotracheal Tube) 7 mm, Venner PneuX™ ETT (Endotracheal Tube) 8 mm, Venner PneuX™ ETT (Endotracheal Tube) 9 mm

Feb 14, 2020
192 days to decision

K192120 · Product code: **BTR** · Anesthesiology
Source: https://www.510kdatabase.net/k192120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Aug 6, 2019
Decision date	Feb 14, 2020
Days to decision	192 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