

K242921 5300600-5301000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, sizes 6.0-10.0mmJun 10, 2025
259 days to decisionK242921 · Product code: **BTO** · Anesthesiology
Source: <https://www.510kdatabase.net/k242921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Sep 24, 2024
Decision date	Jun 10, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	5310600-5311000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, Fenestrated, sizes 6.0-10.0mm; 5400600-5401000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, sizes 6.0-10.0mm; 5410500-5411000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, Fenestrated, sizes 6.0-10.0mm

APPLICANT

Company	Vitaltec Corporation
Location	Hsin Chu City, TW
Contact	Joseph Chang
510(k) history	2 submissions · 2 cleared · 2010-2025

REGULATORY CONSULTANT

Consulting firm	Ruscert Technology Co., Ltd.
Contact	Ming-Yie Jan

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