

K100480 ROTA-TRACH TRACHEOSTOMY TUBE MODEL ROTA-TRACHJun 11, 2010
113 days to decisionK100480 · Product code: **BTO** · Anesthesiology
Source: <https://www.510kdatabase.net/k100480/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tube, Tracheostomy (w/wo Connector) (BTO) |
| Date received | Feb 18, 2010 |
| Decision date | Jun 11, 2010 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vitaltec Corporation |
| Location | Hsin Chu City, TW |
| Contact | JEN KE-MIN |
| 510(k) history | 2 submissions · 2 cleared · 2010-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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