FDA 510(k) Premarket Notification

K053248 SMARTVEST AIRWAY CLEARANCE SYSTEM, MODEL TL

CLEARED

Dec 1, 2005
10 days to decision

K053248 · Product code: **BYI** · Anesthesiology
Source: https://www.510kdatabase.net/k053248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Nov 21, 2005
Decision date	Dec 1, 2005
Days to decision	10 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Electromed, Inc.**
Location	New Prague, MN, US
Contact	CHET SIEVERT
510(k) history	5 submissions · 5 cleared · 1999-2022