FDA 510(k) Premarket Notification

K201026 sOLVe Tube

CLEARED

Aug 10, 2021
477 days to decision

K201026 · Product code: **CBI** · Anesthesiology
Source: https://www.510kdatabase.net/k201026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI)
Date received	Apr 20, 2020
Decision date	Aug 10, 2021
Days to decision	477 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hytek Medical, Inc.**
Location	Northridge, CA, US
Contact	Nir Hoftman
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Allison Komiyama

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