

K210992 Altech® Exhalation Valve (Single Limb and Dual Limb)Dec 23, 2021
265 days to decisionK210992 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k210992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	Apr 2, 2021
Decision date	Dec 23, 2021
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meditera Tibbi Malzeme San VE Tic AS
Location	Izmir, TR
Contact	Cenk Kilic Kalkan
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Meditera Tibbi Malzeme San VE Tic AS C/O Promedic, LLC
Contact	Paul Dryden

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

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