FDA 510(k) Premarket Notification

K171235 OmniCap

CLEARED

Jan 4, 2018
252 days to decision

K171235 · Product code: **CCK** · Anesthesiology
Source: https://www.510kdatabase.net/k171235/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Apr 27, 2017
Decision date	Jan 4, 2018
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respirion, Inc.**
Location	Winston-Salem, NC, US
Contact	Ed Fadel
510(k) history	1 submissions · 1 cleared · 2018-2018