FDA 510(k) Premarket Notification

K120146 QUARK SERIES

CLEARED

Dec 11, 2012
328 days to decision

K120146 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k120146/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jan 18, 2012
Decision date	Dec 11, 2012
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cosmed Srl**
Location	West Cadwell, NJ, US
Contact	ROBERT SCHIFF
510(k) history	10 submissions · 10 cleared · 1997-2020