FDA 510(k) Premarket Notification

K122699 SENTRYSUITE PRODUCT LINE

CLEARED

Nov 19, 2012
76 days to decision

K122699 · Product code: **BTY** · Anesthesiology
Source: https://www.510kdatabase.net/k122699/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Sep 4, 2012
Decision date	Nov 19, 2012
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carefusion Germany 234 GmbH**
Location	Hoechberg, DE
Contact	ELMAR NIEDERMEYER
510(k) history	12 submissions · 12 cleared · 2010-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122699/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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