

K113813 SENTRYSUITE PRODUCT LINEMay 10, 2012
139 days to decisionK113813 · Product code: **BTY** · Anesthesiology
Source: <https://www.510kdatabase.net/k113813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Dec 23, 2011
Decision date	May 10, 2012
Days to decision	139 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.netDevice record: <https://www.510kdatabase.net/k113813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026