

K091871 DK50 DSOct 23, 2009
122 days to decisionK091871 · Product code: **BTI** · Anesthesiology
Source: <https://www.510kdatabase.net/k091871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Compressor, Air, Portable (BTI)
Date received	Jun 23, 2009
Decision date	Oct 23, 2009
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ekom S.R.O.
Location	Dana Point, CA, US
Contact	PAUL DRYDEN
510(k) history	2 submissions · 2 cleared · 2006-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091871/> 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