FDA 510(k) Premarket Notification

K091871 DK50 DS

CLEARED

Oct 23, 2009
122 days to decision

K091871 · 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