FDA 510(k) Premarket Notification

K091732 VRLXP, MODEL XP

CLEARED

Mar 4, 2010
266 days to decision

K091732 · Product code: **OCR** · Anesthesiology
Source: https://www.510kdatabase.net/k091732/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Sound Monitor (OCR)
Date received	Jun 11, 2009
Decision date	Mar 4, 2010
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Deep Breeze , Ltd.**
Location	Washington, DC, US
Contact	JEFF BAETZ
510(k) history	3 submissions · 3 cleared · 2007-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091732/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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