FDA 510(k) Premarket Notification

K073582 VRIICU SYSTEM

CLEARED

Oct 15, 2008
300 days to decision

K073582 · Product code: **OCR** · Anesthesiology
Source: https://www.510kdatabase.net/k073582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Sound Monitor (OCR)
Date received	Dec 20, 2007
Decision date	Oct 15, 2008
Days to decision	300 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