FDA 510(k) Premarket Notification

K111207 RESPIRE BLUE SERIES

CLEARED

Aug 23, 2011
116 days to decision

K111207 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k111207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Anti-snoring (LRK)
Date received	Apr 29, 2011
Decision date	Aug 23, 2011
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respire Medical**
Location	Woodland Hills, CA, US
Contact	DANIELA LEVY
510(k) history	2 submissions · 2 cleared · 2011-2013