FDA 510(k) Premarket Notification

K170692 Respire Pink Series with DentiTrac

CLEARED

May 26, 2017
80 days to decision

K170692 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k170692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Mar 7, 2017
Decision date	May 26, 2017
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respire Medical Holding**
Location	Brooklyn, NY, US
Contact	Jonathan Sandler
510(k) history	3 submissions · 3 cleared · 2015-2017