FDA 510(k) Premarket Notification

K150572 Respire Pink Series-Herbst-EF

CLEARED

Aug 27, 2015
174 days to decision

K150572 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k150572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Mar 6, 2015
Decision date	Aug 27, 2015
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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