FDA 510(k) Premarket Notification

K192127 Respire Pink AT (Hard, Hard/Soft, EF)

CLEARED

Feb 5, 2020
183 days to decision

K192127 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k192127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Aug 6, 2019
Decision date	Feb 5, 2020
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Respire Medical Holdings**
Location	Brooklyn, NY, US
Contact	Madubuike Okafor
510(k) history	1 submissions · 1 cleared · 2020-2020