FDA 510(k) Premarket Notification

K190236 O2Vent Optima

CLEARED

Aug 29, 2019
204 days to decision

K190236 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k190236/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Feb 6, 2019
Decision date	Aug 29, 2019
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oventus Manufacturing Pty, Ltd.**
Location	Brisbane, AU
Contact	Robyn Woidtke
510(k) history	4 submissions · 4 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	**Regulatory and Clinical Research Institute**
Contact	M.W. (Andy) Anderson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov