FDA 510(k) Premarket Notification

K233754 AIO Breathe

CLEARED

Feb 23, 2024
93 days to decision

K233754 · Product code: **LQZ** · Dental
Source: https://www.510kdatabase.net/k233754/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Jaw Repositioning (LQZ)
Date received	Nov 22, 2023
Decision date	Feb 23, 2024
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aiomega, LLC**
Location	Tyler, TX, US
Contact	Raghavendra Ghuge
510(k) history	2 submissions · 2 cleared · 2024-2025