FDA 510(k) Premarket Notification

K221892 VISIONAIR

CLEARED

Oct 5, 2022
98 days to decision

K221892 · Product code: **BXQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k221892/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rhinoanemometer (measurement Of Nasal Decongestion) (BXQ)
Date received	Jun 29, 2022
Decision date	Oct 5, 2022
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pacificmd Biotech, LLC**
Location	Henderson, NV, US
Contact	Jetmir Palushi
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Canyon Labs**
Contact	David M. Locke

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