FDA 510(k) Premarket Notification

K243219 MONARCH™ Platform (MON-000008)

CLEARED

Jan 23, 2025
108 days to decision

K243219 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k243219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Oct 7, 2024
Decision date	Jan 23, 2025
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Auris Health, Inc.**
Location	Redwood, CA, US
Contact	Amy Clendening-Wheeler
510(k) history	4 submissions · 4 cleared · 2020-2025