

K243219 MONARCH™ Platform (MON-000008)Jan 23, 2025
108 days to decisionK243219 · Product code: **EOQ** · Ear, Nose, ThroatSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026