FDA 510(k) Premarket Notification

CLEARED

K260382 MONARCH™ Platform (MON-000008)

Jul 25, 2026
170 days to decision

K260382 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k260382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Feb 5, 2026
Decision date	Jul 25, 2026
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Auris Health, Inc.**
Location	Redwood, CA, US
Contact	James P Garvey II
510(k) history	5 submissions · 5 cleared · 2020-2026