

K211493 Monarch PlatformJul 9, 2021
57 days to decisionK211493 · Product code: **EOQ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k211493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	May 13, 2021
Decision date	Jul 9, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Auris Health, Inc.
Location	Redwood, CA, US
Contact	Shikha Gola
510(k) history	4 submissions · 4 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211493/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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