

K193534 Monarch PlatformApr 15, 2020
117 days to decisionK193534 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k193534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Dec 20, 2019
Decision date	Apr 15, 2020
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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