

**K231473 Monarch Bronchoscope**Nov 28, 2023  
190 days to decisionK231473 · Product code: **QNW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k231473/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Bronchoscope (QNW)
Date received	May 22, 2023
Decision date	Nov 28, 2023
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Auris Health, Inc., A Johnson and Johnson Family Company</b>
Location	Redwood, CA, US
Contact	Somi Ekwealor
510(k) history	2 submissions · 2 cleared · 2021-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231473/> 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 26, 2026