

K203614 Monarch BronchoscopeMar 11, 2021
91 days to decisionK203614 · Product code: **QNW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k203614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Bronchoscope (QNW)
Date received	Dec 10, 2020
Decision date	Mar 11, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203614/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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