

**K213334 Monarch Platform, Urology**Apr 29, 2022  
205 days to decisionK213334 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213334/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Oct 6, 2021
Decision date	Apr 29, 2022
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Auris Health, Inc.</b>
Location	Redwood, CA, US
Contact	Angela Wong
510(k) history	4 submissions · 4 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213334/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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