

**K230312 Iris AirShuttle™**Mar 31, 2023  
56 days to decisionK230312 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k230312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 3, 2023
Decision date	Mar 31, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qfix</b>
Location	Avondale, PA, US
Contact	McKenzie Banasik
510(k) history	7 submissions · 7 cleared · 2015-2023

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