

**K231664 IRRAfFlow Active Fluid Exchange System (AFES)**Oct 19, 2023  
134 days to decisionK231664 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k231664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jun 7, 2023
Decision date	Oct 19, 2023
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Irras USA, Inc.</b>
Location	San Diego, CA, US
Contact	Jeanne S. Warner
510(k) history	2 submissions · 2 cleared · 2020-2023

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