

K222471 IRRAfFlow Active Fluid Exchange System (AFES)Dec 8, 2022
114 days to decisionK222471 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k222471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Aug 16, 2022
Decision date	Dec 8, 2022
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Irras USA
Location	San Diego, CA, US
Contact	Jeanne S Warner
510(k) history	1 submissions · 1 cleared · 2022-2022

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