

K200807 IRRAfFlow Catheter, IRRAfFlow Tube Set, IRRAfFlow Control UnitApr 29, 2020
33 days to decisionK200807 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k200807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Mar 27, 2020
Decision date	Apr 29, 2020
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Irras USA, Inc.
Location	San Diego, CA, US
Contact	Niloufa Insanally
510(k) history	2 submissions · 2 cleared · 2020-2023

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