

K192289 IRRAfFlow Catheter, IRRAfFlow Tube Set, IRRAfFlow Control UnitNov 15, 2019
84 days to decisionK192289 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k192289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Aug 23, 2019
Decision date	Nov 15, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Irras USA, Ltd.
Location	San Diego, CA, US
Contact	Vinny Podichetty
510(k) history	1 submissions · 1 cleared · 2019-2019

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