

K212340 EMBOGUARD Balloon Guide CatheterDec 17, 2021
142 days to decisionK212340 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k212340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Jul 28, 2021
Decision date	Dec 17, 2021
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neuravi Limited
Location	Galway, IE
Contact	Niall Fox
510(k) history	3 submissions · 3 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212340/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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