

K223275 CELLO II Balloon Guide CatheterDec 9, 2022
46 days to decisionK223275 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k223275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Oct 24, 2022
Decision date	Dec 9, 2022
Days to decision	46 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fuji Systems Corporation
Location	Nishi Shirakawa Gun, JP
Contact	Yoshiyuki Suzuki
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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