

K231711 microINR SystemJul 11, 2023
29 days to decisionK231711 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k231711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jun 12, 2023
Decision date	Jul 11, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iline Microsystems, S.L.
Location	Donostia-San Sebastian, ES
Contact	Miren Itsaso Hormaeche
510(k) history	5 submissions · 5 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231711/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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