

K243543 microINR SystemFeb 27, 2025
104 days to decisionK243543 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k243543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Nov 15, 2024
Decision date	Feb 27, 2025
Days to decision	104 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

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