

**K251564 microINR System**Jul 21, 2025  
60 days to decisionK251564 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k251564/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	May 22, 2025
Decision date	Jul 21, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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