

K201185 microINR SystemDec 18, 2020
231 days to decisionK201185 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k201185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	May 1, 2020
Decision date	Dec 18, 2020
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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