

K213426 HemosIL ReadiplasTinAug 16, 2022
299 days to decisionK213426 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k213426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Oct 21, 2021
Decision date	Aug 16, 2022
Days to decision	299 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	Carol Marble
510(k) history	321 submissions · 320 cleared · 1976-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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