

K230852 HemosIL Chromogenic Factor IXDec 13, 2023
260 days to decisionK230852 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k230852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Mar 28, 2023
Decision date	Dec 13, 2023
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory Company
Location	Bedford, MA, US
Contact	Carol Marble
510(k) history	3 submissions · 3 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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