

**K090563 HEMOSIL INR VALIDATE, HEMOSIL ISI CALIBRATE,
ISIWEB (SOFTWARE)**Oct 9, 2009
221 days to decisionK090563 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k090563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Mar 2, 2009
Decision date	Oct 9, 2009
Days to decision	221 days
Third-party review	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/k090563/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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