

K231031 ACL TOP Family 70 SeriesJun 21, 2023
71 days to decisionK231031 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k231031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Apr 11, 2023
Decision date	Jun 21, 2023
Days to decision	71 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

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