

K160445 HemosIL Silica Clotting TimeMar 16, 2016
28 days to decisionK160445 · Product code: **GFO** · Hematology
Source: <https://www.510kdatabase.net/k160445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Feb 17, 2016
Decision date	Mar 16, 2016
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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