

K160885 HemosIL D-Dimer HS

Oct 27, 2016
210 days to decision

K160885 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k160885/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Mar 31, 2016
Decision date	Oct 27, 2016
Days to decision	210 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

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Device record: <https://www.510kdatabase.net/k160885/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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