

K180486 HemosIL Factor XII Deficient PlasmaMar 22, 2018
27 days to decisionK180486 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k180486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Feb 23, 2018
Decision date	Mar 22, 2018
Days to decision	27 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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