

K181525 INNOVANCE Free PS AgSep 7, 2018
88 days to decisionK181525 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k181525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jun 11, 2018
Decision date	Sep 7, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products GmbH
Location	Marburg, DE
Contact	Petra Dissmann
510(k) history	19 submissions · 18 cleared · 2016-2024

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