

K063323 SPECTROLYSE PAI-1, MODEL 101201Aug 15, 2007
285 days to decisionK063323 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k063323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 3, 2006
Decision date	Aug 15, 2007
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Diagnostica, Inc.
Location	Greenwich, CT, US
Contact	DAVID TEICHER
510(k) history	10 submissions · 10 cleared · 1994-2008

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