

K952252 ADP REAGENT, MODIFIEDSep 8, 1995
116 days to decisionK952252 · Product code: **GHR** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Platelet Aggregation (GHR)
Date received	May 15, 1995
Decision date	Sep 8, 1995
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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